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Subdivision U is one of a series of the Pesticide Assessment Guidelines whose purpose is to aid pesticide registrants and others in designing and carrying out field studies which measure, using personal monitoring techniques, potential dermal and respiratory exposure to pesticides when used according to widespread and commonly recognized practice.

These guidelines address direct exposure encountered during any pesticide application operation and related occupational activities including weighing and mixing the concentrated chemical, loading the material into the application equipment, etc. These guidelines also include indoor testing procedures to measure post-application exposure to persons as a result of indoor use of pesticides. However, post-application exposure to workers as a result of outdoor uses is covered in Subdivision K - Reentry Guidelines.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION U

APPLICATOR EXPOSURE MONITORING

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Preamble

The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) released a draft of Subdivision U of the Pesticide Assessment Guidelines to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) on January 2, 1986 (51 FR 2568). A set of six questions related to this draft document was also submitted for comment. The SAP met in open session to discuss this document in Arlington, Virginia on February 12, 1986. The transcript of this meeting, along with the questions posed by the Agency and the SAP's responses are contained in public docket nos. 3-36108 and 4-36108.

The January 2, 1986 draft of Subdivision U was also released for a sixty day public comment period (51 FR 3505) which ended March 31, 1986. Comments were received as follows: Dr. Richard Fenske of Rutgers University (docket no. 1-36108); Dr. Earl Spurrier representing the National Agricultural Chemicals Association (docket no. 2-36108); Dr. Nancy Muir representing Health and Welfare Canada (docket no. 5-36108); and Dr. Douglas Baugher of Orius Associates (docket no. 6-36108).

The SAP and public comments and their disposition by the Agency (docket no. 7-36108) may be obtained from: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460. Please identify requests using the document control number (OPP-7-36108).

§I. Purpose

Individuals who have contact with pesticides in the course of their work activities will be exposed to these chemicals through different routes and to a different extent than the general population. Subdivision U is one of a series of the Pesticide Assessment Guidelines whose purpose is to aid pesticide registrants and others in designing and carrying out field studies which measure, using personal monitoring techniques, potential dermal and respiratory exposure to pesticides when used according to widespread and commonly recognized practice.

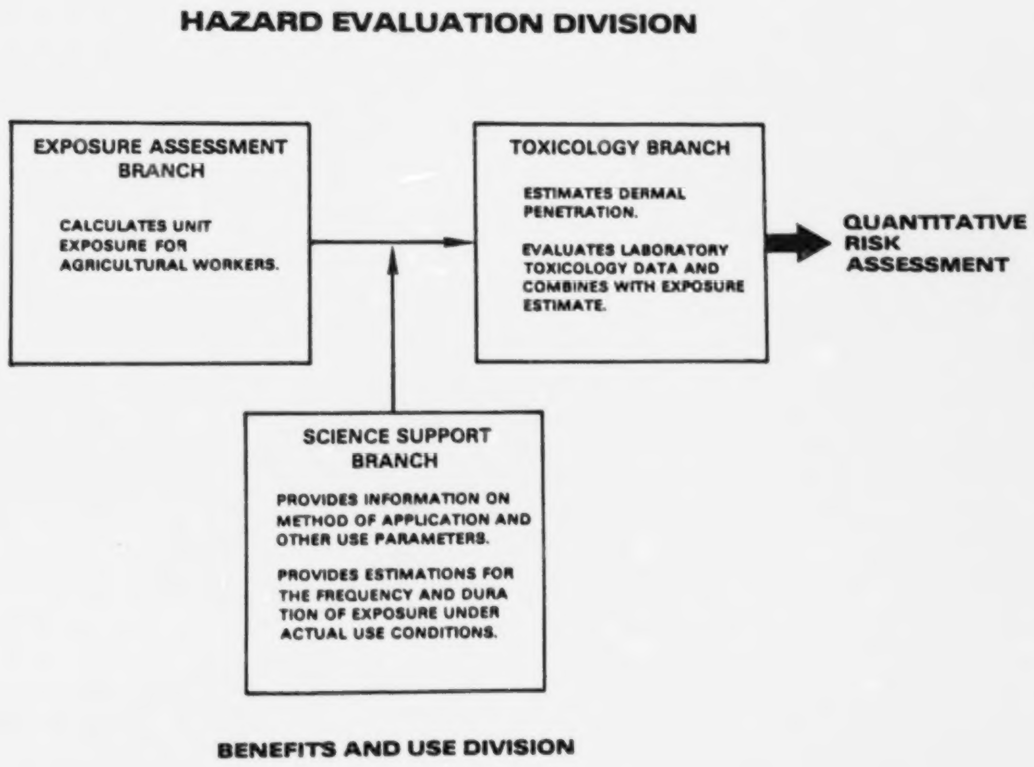
These guidelines address direct exposure encountered during any pesticide application operation and related occupational activities including weighing and mixing the concentrated chemical, loading the material into the application equipment, etc. These guidelines also include indoor testing procedures to measure post-application exposure to persons as a result of indoor use of pesticides. However, post-application exposure to workers as a result of outdoor uses is covered in Subdivision K - Reentry Guidelines.

§II. FIFRA and Applicator Exposure - A Regulatory Overview

The organization of this section is similar to that of two recent publications (May, 1984; EPA 1985a). The increasing concern over pesticides in the environment during the 1960's caused a shift in the thrust of pesticide regulation from one of efficacy (protection of pesticide users from fraudulent product claims) to one of protection of the environment and public health. The legislative basis for the regulation of pesticides is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This Act was amended significantly in 1972 with the creation of a criterion set forth to prevent "unreasonable adverse effects on the environment." This is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." Amendments to FIFRA in 1975, 1978 and 1980 have not altered this basic risk criterion for regulatory decision making.

An organizational overview of the risk assessment process in the Office of Pesticide Programs (OPP) is shown in Figure 1-1. Physical scientists in the Exposure Assessment Branch (EAB) of the Hazard Evaluation Division (HED) of OPP have the responsibility for estimating actual worker exposure. Agricultural scientists in the Science Support Branch (SSB) of OPP's Benefits and Use Division (BUD) supply pertinent use information along with estimates of the frequency and

Figure 1-1. Organizational Overview of the Risk Assessment Process in the Office of Pesticide Programs


HAZARD EVALUATION DIVISION
EXPOSURE ASSESSMENT BRANCH
CALCULATES UNIT EXPOSURE FOR AGRICULTURAL WORKERS.
TOXICOLOGY BRANCH
ESTIMATES DERMAL PENETRATION.
EVALUATES LABORATORY TOXICOLOGY DATA AND COMBINES WITH EXPOSURE ESTIMATE.
QUANTITATIVE RISK ASSESSMENT
SCIENCE SUPPORT BRANCH
PROVIDES INFORMATION ON METHOD OF APPLICATION AND OTHER USE PARAMETERS.
PROVIDES ESTIMATIONS FOR THE FREQUENCY AND DURATION OF EXPOSURE UNDER ACTUAL USE CONDITIONS.
BENEFITS AND USE DIVISION

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duration of each application activity for which an exposure assessment is prepared. The estimated exposure for the required time interval (daily or annually depending on whether the assessment is for an acute or chronic toxicological concern) is given to HED's Toxicology Branch (TB), where it is considered along with the results of the biological effects studies to produce a quantitative risk assessment. The risk assessment is considered in the risk/benefit analysis required for regulatory decisions under FIFRA.

To implement the 1972 amendments to FIFRA, the Agency developed the Rebuttable Presumption Against Registration (RPAR) process and published the criteria which trigger the detailed determination of unreasonable adverse effects associated with a given pesticide use (EPA, 1975). At the onset of the RPAR process it was apparent that the risks to individuals who apply pesticides are distinct from those to the general population, and must be considered under the broad umbrella of the unreasonable adverse effects criterion (EPA, 1978; 1979a; 1979b; 1979c).

It became apparent during the early RPARs that few data were available for estimating the occupational exposure of pesticide applicators and mixer/loaders. The components of a quantitative risk assessment are hazard assessment, usually a study of the toxicological response of laboratory animals to a chemical, and exposure. Occupational exposure could not generally be estimated with any certainty. A committee of the National Research Council (NRC), commissioned with the task of analyzing the effectiveness of the RPAR process, noted (NRC, 1980):

> In estimating exposure, as in other phases of its work, OPP is constantly hampered by lack of adequate data, and is forced to resort to indirect and inaccurate methods in its effort to make plausible estimates.

A 1978 amendment to FIFRA emphasized the importance of accurately evaluating exposure in OPP's regulatory decisions. Section 3(c)(8) was added to FIFRA and states (in part):

> Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such a pesticide, required under this Act,

> unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment.

While "exposure" does not appear in this section of FIFRA, this is clearly what Congress intended with the phrase "prudent concerns of unreasonable adverse risk." The House-Senate Conference Report discussing this section of the 1978 amendments (Conference Report, 1979) states:

> Human exposure to pesticides through any medium or pathway is a central issue in evaluating the unreasonable adverse effects of pesticide products. Where this issue can be resolved without an RPAR being initiated, it shall be.

In discussing the amendments, Rep. Foley stated (Congressional Record, 1978):

> To avoid the time consuming RPAR process, the Administrator is directed to establish suitable scientific protocols for development of human exposure data . . . and then to evaluate and weigh such data prior to initiating an RPAR process.

The RPAR triggers promulgated in 1975 were based solely on toxicological hazards and did not take exposure into account. These triggers have now been replaced by new criteria initiating the assessment of unreasonable adverse effects which do consider the likely level of exposure. The RPAR process is now called the "Special Review" process (EPA, 1985a).

A consequence of the 1978 amendments to FIFRA is that applicator risk assessments, traditionally done only for registered pesticides under RPAR review, must now be undertaken for pesticides undergoing registration or reregistration (Registration Standard) review as well as Special Review, when a potential toxicological concern has been identified.

While the unreasonable adverse effects criterion of FIFRA does not make a distinction between indoor and outdoor uses of pesticides, historically most regulatory attention has been focused on the outdoor uses of pesticides (Reinert, 1984). The review of many of the older, persistent pesticides used on food crops has been very resource-intensive and has lessened the Agency's ability to address concurrently the indoor uses. With the recent increased concern for human health and the indoor environment (Spengler and Sexton, 1983), activity in the areas of monitoring and evaluating the indoor uses of pesticide chemicals has increased.

Consequently, these guidelines will cover exposure monitoring studies for both outdoor and indoor sites. For many indoor uses, the individual who applies the pesticide also works or resides in the building. As stated in the previous section, indoor exposure to pesticides is not currently addressed in other subdivisions of these guidelines. Accordingly, both application and ambient exposure will be addressed for indoor uses.

§III. Monitoring Exposure Using Passive Dosimetry and Biological Monitoring

A. Definitions

Passive dosimetry estimates the amount of a chemical impinging on the surface of the skin or the amount of the chemical available for inhalation through the use of appropriate trapping devices.

Biological monitoring estimates internal dose from either a measurement of body burden in selected tissues or fluids or from the amount of pesticide or its metabolites eliminated from the body.

B. Theoretical and practical advantages and disadvantages of both approaches

1. Passive dosimetry

Traditionally, applicator exposure monitoring studies carried out for the Agency have employed passive dosimetry techniques. Because of this history of use, experimental design and execution of exposure studies by passive dosimetry are routine for many investigators.

The major advantages of direct entrapment procedures are the ability to differentiate exposure received during discrete work activities within a work day and in differentiating the relative contributions of the dermal and respiratory exposure routes for each separate work activity (Durham, 1985). These advantages are extremely important for evaluating exposure reduction safety practices such as personal protective equipment for the various work activities associated with pesticide application. For example, if a substantial fraction of total exposure for a work day occurs to the hands, forearms and face during the short period of time a worker pours a concentrated pesticide formulation into a mix tank, risk may be mitigated significantly by requiring chemical resistant gloves, a face shield, and/or a closed mixing system for this short duration/high exposure period. Since passive dosimetry measures only the amount of chemical potentially available for absorption, independent estimates of dermal and lung absorption are required to estimate dosage for hazard assessment purposes. These absorption estimates are generally difficult to derive and interpret using data available from either in vivo or in vitro penetration studies. In addition, when using passive dosimetry, assumptions concerning the value of the clothing worn on the interception of pesticide residues must also be made.

A potential source of error in the use of patches for sample collection is the extrapolation from the residues on the relatively small surface area of the trapping devices to entire body surface areas. Also, when using the patch technique, crucial areas of exposure may be missed depending on the location of the trapping devices (Franklin et al., 1981).

A unique advantage of passive dosimetry is the ability to create large generic data bases from studies carried out with different pesticides. The use of the generic approach is discussed in detail in Section VI of these guidelines. Another advantage in using passive dosimetry is that the study participants are typically under the supervision of the investigator during the entire period when exposure data are being collected.

A more detailed description of the methods used in passive dosimetry is contained in Section V.

2. Biological monitoring

The distinct theoretical advantage of the biological monitoring approach is that, under proper conditions, actual dose may be estimated from the results of the monitoring study.

Biological monitoring implies that a biological measurement is intrinsic to the experimental design of an exposure assessment study. The use of the information derived from biological monitoring studies varies, from the early detection of a health effect to establishing a correlation between concentration of a chemical in fluids to absorbed dose.

An example of the application of biological monitoring to the detection of a health effect is the analysis of cholinesterase levels in blood as an indicator of worker exposure to organophosphate pesticides (Peoples and Knaak, 1982). In this approach, medical surveillance of workers allows the expedient implementation of preventive measures, as dictated by blood cholinesterase inhibition levels (Quinby et al., 1958; Kay et al., 1952). A quantification of exposure from cholinesterase inhibition is not a goal in this situation.

Attempts to correlate levels of cholinesterase inhibition with concentrations of parent pesticides or their metabolites in either blood or urine have not been successful (Bradway et al., 1977; Roan et al., 1969; Drevenkar et al., 1983). A major contributor to this failure is the wide variability of cholinesterase levels among individuals (Popendorf and Leffingwell, 1982). In its current practice, this type of medical surveillance is carried out by establishing a baseline, pre-exposure level for each worker and an arbitrary inhibition level is set at which the worker is removed from further exposure.

Correlations between levels of exposure and concentrations of metabolites in blood have been documented for some industrial chemicals. The parameter monitored in this case is the formation of covalent adducts between the chemical, or a metabolite, and hemoglobin. (Tannenbaum and Skipper, 1984; Pereira and Chang, 1982). Examples reported in the literature where this technique has been applied include ethylene oxide (Calleman et al., 1978), chloroform (Pereira and Chang, 1982), and aniline (Neumann, 1984). The route of exposure in these cases was predominantly inhalation.

The basis for this approach is the ability of the chemical to alkylate hemoglobin. The reaction may take place directly as with ethylene oxide or may require metabolic activation to a reactive species as reported for chloroform and aniline.

The selection of hemoglobin as an internal dosimeter is based on several features: 1) hemoglobin contains nucleophilic groups, histidine and cysteine, thus maximizing trapping efficiency; 2) hemoglobin is readily available in large amounts; and 3) the life span of hemoglobin, and its adducts, is about 18 weeks in humans, providing a stable marker for monitoring work environments which could be particularly useful for situations involving low-level chronic exposure.

The reaction rate constants for the alkylation reaction of electrophiles with hemoglobin can be determined in vitro and may be used in conjunction with the adduct concentration to estimate the in vivo dose. At this time, this type of analysis has been fully documented in humans only in the case of exposure to ethylene oxide. For a group of workers handling ethylene oxide sterilizers, a correlation was established between external exposure dose and the amount of covalent adduct formed per gram of hemoglobin (Calleman et al., 1978).

A different approach, which does not require the intermediacy of reactive species, involves the measurement of concentrations of parent chemical(s) and/or corresponding metabolites in urine (Aitio, et al., 1984; Baselt, 1980). Empirical correlations have been developed for some industrial chemicals which allow estimation of the exposure based on the rate of urinary excretion of selected markers. Through the application of biological monitoring to industrial settings, it has become possible to identify workers at high risk and proceed to modify the operations or conditions leading to an undesirable high exposure.

For pesticides, urinary metabolites have been used to detect exposure during field operations. Swan (1969) measured paraquat in the urine of applicators; Gollop and Glass (1979) and Wagner and Weswig (1974) measured arsenic in timber applicators; Lieben et al. (1953) and Durham and Wolfe (1962) measured para-nitrophenol in urine after parathion exposure. A chlorobenzilate metabolite was detected in citrus workers (Levy et al., 1981), phenoxy acid herbicide metabolites in farmers, (Kolmodin-Hedman et al., 1983b) and organophosphate metabolites in the urine of people exposed to mosquito treatments (Kutz and Strassman, 1977). Davies et al. (1979) used urine metabolites of organophosphates and carbamates to confirm poisoning cases. These studies documented exposure, but no quantification of exposure was typically made from urinary metabolites alone.

Because applicators are often exposed to the same pesticide numerous times over a growing season, proper interpretation of urine data is difficult unless the pesticide is excreted fairly rapidly or multiple dosing and overlapping excretion patterns are well understood.

Some experiments have contributed to understanding these problems and illustrate typical differences in the rate of absorption and excretion of various pesticides. Drevenkar et al. (1979) studied the excretion of phosalone metabolites in one volunteer. Excretion reached a peak in 4-5 hours, and was not complete in 24 hours. Funckes et al. (1963) exposed the hand and forearm of human volunteers to 2 percent parathion dust. During the exposure the volunteers breathed pure air and placed their forearm and hand into a plastic bag which contained the parathion. The exposure took place for 2 hours and at various temperatures. There was increased excretion of p-nitrophenol with increasing temperature. More importantly, p-nitrophenol could be detected in the urine 40 hours later.

In another human experiment, Kolmodin-Hedman et al. (1983b) applied methylchlorophenoxyacetic acid (MCPA) to the thigh. MCPA appeared in the urine for 5 days with a maximum concentration in about 48 hours. When administered orally, MCPA peaked in urine in one hour and about 40 percent of the dose was excreted in 24 hours.

Seven different organophosphates were fed to rats at two doses for three days. The rats were removed from exposure after the third day, and urine was collected for the next ten days (Bradway et. al, 1977). The percent of the total dose excreted in urine over ten days averaged (high and low doses): dimethoate 15%; dichlorvos 10%; ronnel 11%; dichlofenthion 57%; carbophenothion 67%; parathion 41%; and leptophos 52%. Very little of this excretion occurred beyond the third day after exposure.

In another experiment, rats were dosed dermally and intramuscularly with azinphosmethyl (Franklin et al., 1983). About 78% of the dermal dose had been excreted in urine in 24 hours. For the intramuscular dose the rate of excretion peaked in 8-16 hours, continued at about the same rate for 16 hours and declined to a steady level in 48 hours. There was a linear relationship between dose and urinary excretions.

While biological monitoring theoretically offers a distinct advantage, there are inherent difficulties in study design, execution, and data interpretation. Prior to establishing specific testing procedures, the experimenter must have a broad knowledge of the chemical being tested. The pharmacokinetics of the chemical of interest must be known and fully understood so that the appropriate tissue, fluid, or excretion pathway, as well as the appropriate time periods for monitoring, can be chosen with regard to this information. Because this level of detailed information is currently unavailable for many pesticides, extrapolations back to the actual dose are difficult.

When measuring exposure via a human substrate one must consider the different ways through which a substance may be eliminated (sweat, urine, saliva, etc.) or that it may be stored in adipose and other tissues. Because the measurements relevant to the estimation of workers' exposure to pesticides must be carried out under field conditions, the Agency believes that urine analysis is a realistic and practical approach to implement biological monitoring. This emphasis on a particular method is based on a consideration of the type of information desired and what is feasible to obtain under field conditions. It should be understood, however, that this observation is not intended to exclude other methods which are demonstrably effective.

Biological monitoring clearly lacks the definition of source of exposure provided by the passive dosimetry method. The results of an appropriate biological monitoring study provide an integrated exposure picture. Biological monitoring should be considered a chemical specific approach. The potential for extrapolating results of an exposure study to other pesticides appears limited by probable differences in absorption, metabolism and excretion profiles. Thus the opportunity for developing generic data bases, such as those from passive dosimetry studies, does not appear promising. This difficulty, however, may be overcome by the application of structure activity principles which would allow the grouping of pesticides according to chemical descriptors, thus providing a reasonable foundation for a useful, predictive data base.

A potential difficulty that may be encountered when using a biological method is obtaining strict cooperation and adherence to protocols from study participants when collecting samples (urine, saliva, etc.). Monetary incentives are sometimes needed to increase cooperation. This may be true particularly when monitoring requires invasive collection techniques such as blood sampling. Invasive techniques could also raise legal and medical questions associated with the field collection of human tissues and fluids.

A plan for intensive study oversight is necessary to ensure participant compliance in collection, storage and handling of urine samples including before, during, and after exposure to pesticides. It is not always practical, however, since investigators are usually on site during the work activities only, while exposure data are collected beyond the supervised period.

When a registrant believes that the problems associated with biological monitoring as described in this section can be overcome for a particular pesticide and chooses to monitor worker exposure using biological monitoring, the Agency will carefully evaluate the results and, if judged valid, use the results in the risk assessment process. In these circumstances, the theoretical advantage of biological monitoring discussed earlier in this section would naturally dictate the use of such data. Prior to initiating a biological monitoring study, however, the registrant must receive Agency approval of the study protocol.

An examination of the limitations of the trapping devices presently used in passive dosimetry has suggested exposure scenarios where it would be necessary to utilize biological monitoring to estimate exposure. Examples of specific situations not amenable to current passive dosimetry methodologies include measuring exposure to pesticides in swimming pools, in dishwashing detergents, or measuring dermal exposure to volatile organic chemicals.

The perceived advantages and disadvantages of passive dosimetry and biological monitoring are summarized in Table 1-1. The observations listed in Table 1-1 may be considered as initial guidance in determining the feasibility of conducting an exposure study by either method.

C. Problems with the simultaneous use of passive dosimetry and biological monitoring

The simultaneous application of passive dosimetry and biological monitoring has been explored by several groups. Attempts have been made to establish a correlation of exposure measurements by both methods. Passive dosimetry has been combined with urinary metabolite determinations to compare worker exposure as a function of application method (Wojeck et al., 1983; Carmen et al., 1982), formulating plant worker exposure (Comer et al., 1975) and homeowner exposure (Staiff et al., 1975). Numerous other studies have similarly attempted to correlate exposure estimates obtained by the use of patches with urine levels of pesticide and/or its metabolite(s) (Lavy et al., 1980b, 1982; Franklin et al., 1981, 1986; Wojeck et al., 1981, 1982, 1983). In most of these studies, no clear cut correlation was found between exposure estimated by both methods.

A recent publication by Franklin et al. (1986) reported a good correlation between urinary metabolites and amount of active ingredient (azinphosmethyl) sprayed. More relevant to the subject, a comparison was also made between dermal exposure estimates derived from urinary metabolites and patches for the same studies. Both methods gave comparable estimates at one application rate, but biological monitoring proved more responsive to variations in the application rate. For two application rates differing by a factor of 2.5, passive dosimetry estimated essentially identical dermal exposure while biological monitoring estimates reflected the difference in application rates. It should be noted, however, that the results reported in the Franklin study were obtained by the concurrent application of passive dosimetry and biological monitoring methods on the same individuals. Unfortunately, the results as obtained did not allow a conclusive assessment of potential interferences arising from the simultaneous use of both monitoring approaches. This concern is discussed in more detail in the following paragraph.

A careful analysis of the information available on the simultaneous use of passive dosimetry and biological monitoring suggests that if a registrant chooses the latter for

Table 1-1. The Perceived Advantages and Disadvantages of Estimating Occupational Exposure with Passive Dosimetry and Biological Monitoring

	ADVANTAGES	DISADVANTAGES
Passive Dosimetry	*routes and areas of exposure clearly defined •routine experimental design and execution •participant under supervision of investigator •generic data bases may be created	*dermal and respiratory absorption must be estimated •extrapolation from patch to body surface area must be made •not all exposure scenarios are amenable
Biological Monitoring	*actual dose may be measured •unnecessary to adjust for value of garment/ protective clothing	*pharmacokinetics must be known •routes of exposure cannot be distinguished •difficult to ensure participant cooperation •potential problems when using invasive techniques required for specimen collection

Bullets highlighted with a "*" are considered most important.

exposure measurements, then no direct dermal exposure methods should be used concurrently on the same individuals. This becomes necessary because the trapping devices used in passive dosimetry for estimating dermal exposure, by definition, intercept chemical residues. This prevents potential absorption, introducing an unnecessary and potentially confounding variable into the study. Until proper experimentation clarifies this situation, the Agency discourages the concurrent use of passive dosimetry and biological monitoring on the same individual in exposure studies.

It may be possible to design a study that would allow correlation between passive dosimetry and biological monitoring methods. An example might be to alternate the two monitoring methods, using the same group of individuals and allowing enough time in between so as to minimize possible interference. The Agency strongly encourages research in the area of comparing exposure estimated by passive dosimetry and biological monitoring.

Specific criteria which must be met before proceeding with an exposure study are described in Sections 231-234 for passive dosimetry and in Section 235 for biological monitoring.

§IV. New Approaches to Field Studies Using Passive Dosimetry

A. Method development

Improving test methodology for measuring exposure, as in all areas of scientific research, is an ongoing process. However, little progress has been made in developing new methodology post Durham and Wolfe. The Agency strongly encourages new method development and stresses that the methodologies detailed herein are subject to change. Research in developing innovative and more efficient ways of measuring dermal and inhalation exposure would be of obvious benefit to those estimating the level of risk to persons handling pesticides.

B. Examples of recent developments

Several alternative methods have recently been developed and used in the field. The World Health Organization (1982) proposed the use of entire portions of garments, rather than patches, to test dermal exposure. This approach has distinct advantages and disadvantages.

One advantage of collecting residues using clothing that covers an entire part of the body is that it provides a more thorough representation of the areas being measured, thus eliminating the uncertainty associated with extrapolation from pads.

Unfortunately, it is very difficult to change clothing or underclothing after each exposure period under conditions usually encountered in the field. Also, it is nearly impossible to remove these garments without contaminating them with residues from other areas of the body, especially those on the workers' hands and hair. When using entire items of clothing, adequate preextraction of interfering additives requires large volumes of solvent, extensive extraction equipment, and lengthy extraction periods. These problems also arise when extracting the items of clothing from the field in the laboratory.

Experimentation may lead to the discovery of methods that could make exposure monitoring less troublesome and more accurate. An example is the measurement of exposure to fumigants. Popendorf et al. (1983) used charcoal impregnated cloth (hand dosimeters) to measure hand exposure to 1,3-dichloropropene. The treated cloth measures dermal exposure to ambient air levels as well as direct contact. The hand dosimeter introduces an alternative method of measuring hand exposure that may lessen the burden of a troublesome task.

Fluorescent tracers may be useful in quantifying exposure beneath clothed areas. Franklin et al. (1981) added Fluorescent Whitening Agent (FWA) to azinphosmethyl in the spray mixture. After removing the exposed pads and clothing, each applicator was examined with ultraviolet light. Unclothed areas such as the face and neck were not monitored with pads, but the tracer revealed that these were significant areas of exposure. The tracer was also found beneath the protective and ordinary clothing, confirming the qualitative penetration of dye, and supporting the concept that there may have been penetration of azinphosmethyl as well.

A similar experiment was conducted by Fenske et al. (1984, 1985). Three hundred grams of the tracer 4-methyl-7-diethylaminocoumarin were added to each 5 pound bag of diazinon 50 percent wettable powder. The tracer concentration on the exposure pads and on the subjects was evaluated through a scanning television apparatus. There was a discrepancy in the amount of tracer actually found on the face and the amount that had been estimated. The pad technique estimated much more exposure to the head than the tracer indicated.

New approaches for measuring applicator exposure will be accepted if they can be shown to be comparable or superior to the methods described in these guidelines. Registrants are encouraged to explore and then discuss new approaches and techniques with the Agency before submitting protocols for approval.

§V. Measuring Applicator Exposure: A Historical Perspective

Shortly after the first acutely toxic synthetic insecticide, parathion, became widely used in agriculture, a number of worker poisonings resulted. It became evident that quantification of occupational exposure to pesticides would be a vital link to evaluating worker safety. In order to minimize occupational exposure to pesticides, it was necessary to determine the routes and amounts of exposure that workers received while engaged in various activities.

The first pesticide exposure study was reported by Griffiths, Stearns, and Thompson (1951). They determined the amounts of parathion trapped on respirator filter discs to compare the exposure received during applications to citrus, by either hand spray guns or airblast sprayers. Batchelor and Walker (1954) expanded exposure monitoring by including pads attached to workers' clothing to estimate potential dermal exposure. This allowed the determination of both the total potential for exposure associated with various tasks and the relative contribution by the dermal and respiratory routes. Durham and Wolfe (1962) reviewed all methodology that had been used to monitor pesticide exposure and provided some experimental validation for the best of that methodology. Subsequent to these pioneering studies, a number of investigators have utilized minor modifications of the original monitoring technique. However, little significant improvement in the accuracy of exposure assessment has been provided by these modifications.

With the advent of the Rebuttable Presumption Against Registration (RPAR) process by the Environmental Protection Agency (EPA), the ultimate use of exposure monitoring data was drastically changed. It could no longer be used simply as a basis for the recommendation of the safest application procedures or as a guide for dealing with acutely toxic hazards. Now, quantitative assessments of risk for specific deleterious effects are required. These effects may be the result of a subtle physiological event resulting from chronic exposure. Therefore, the exposure workers will receive during use of pesticides must be estimated as reliably as possible. The purpose of these guidelines is to suggest the best methods currently available for this estimation.

Most of the methods recommended in these guidelines have been extensively reviewed elsewhere (Durham and Wolfe, 1962; Wolfe, 1976; and Davis, 1980) and the following borrows heavily from those reviews. They are repeated to provide the users of these guidelines with a single source of historical information and a justification for the selected methods. Some of the more recently developed methods currently in use may prove superior to those detailed in these guidelines. The methods discussed here have been shown to be satisfactory in field use and were used to collect the majority of exposure data available at this time. Other methodologies demonstrated to be effective will of course be accepted by the Agency.

The following abbreviated review of exposure monitoring by passive dosimetry is divided into dermal and respiratory exposure, with major emphasis on the former. Dermal monitoring is subdivided into exposure for all areas of the body with a separate section for hand exposure. Also included under dermal monitoring are the body surface area values and a discussion of exposure due to the penetration of clothing by pesticides.

A very important consideration that must be kept in mind when selecting methods for exposure monitoring is that the monitoring method should not subject the participants to any more exposure than is absolutely necessary. For instance, if the pesticide label specifies that respirators that have been approved by the National Institute for Occupational Safety and Health (NIOSH) must be worn during application, no method may require a participant to wear a respirator that would provide less protection. Every monitoring method must be chosen to ensure that human safety will not be compromised.

A. Dermal exposure monitoring

1. Monitoring of exposure to all areas of the body except the hands

The amount of pesticide potentially available for absorption through the skin of a worker can be estimated by trapping the material before it contacts the skin, or by removing material that has contacted the skin before it has been absorbed. This is done using various types of pads or articles of clothing to trap impinging residues, or by removing residues from the skin by swabbing or rinsing with an appropriate solvent.

A major portion of currently available data concerning dermal exposure to pesticides was collected using alpha-cellulose and multi-layered gauze pads described by Durham and Wolfe (1962). However, other investigators have employed cellulose filter paper discs (Batchelor and Walker, 1954), combined filter paper and surgical gauze pads (Lavy et al., 1980a), entire items of clothing (Miller et al., 1980), patches cut from various types of fabric and backed with surgical gauze to collect residues that penetrate the fabric (Knaak et al., 1978), skin swabbing (Durham and Wolfe, 1962), and pads impregnated with lanolin to simulate the slightly greasy surface of the skin (Fletcher et al., 1959).

If pads are used to entrap residues that would have impinged on the skin, the material used for construction of the pads must be absorbent enough to retain all the liquid that contacts them, or, if used for collecting dusts or dried residues, must be porous enough to collect these materials. The pads must be strong enough to hold up under the abuse they will receive in the field. They must not contain additives such as sizing that will interfere with the chemical analysis of extracted residues. Additives can usually be removed by preextraction of the pads. However, some interfering compounds cannot be adequately removed to allow analysis of low levels of residue. Cellulose filter paper pads are usually unsatisfactory because they are quickly saturated with spray and do not have the necessary mechanical strength.

Pads constructed from several layers of filter paper covered with multiple layers of surgical gauze may eventually prove to be a superior monitoring device. The filter paper readily absorbs liquids while the gauze collects impinging dry residues and provides extra mechanical strength. Unfortunately, use of this type of pad under actual field conditions has been rather limited. Therefore, data regarding the trapping efficiency of these pads is also limited.

Another problem encountered when using external pads to monitor dermal exposure is the need to estimate how much of the material collected on the pads would have eventually penetrated clothing. Monitoring dermal exposure with pads constructed from squares of fabric backed by an absorbent pad can provide the investigator with a rough estimate of how much residue would have penetrated through the clothing to the skin of the worker. However, there are also problems associated with this type of pad. Pretreatment of the fabric, special finishes, and the type of fabric used can influence the collection, retention and penetration of residues. Also, use of this type of pad only provides simulation of the penetration of residues through freshly laundered clothing during the first exposure period of the day. These problems will be discussed in greater detail in Section A(4)b, concerning exposure due to residues that penetrate clothing.

Some dermal exposure monitoring techniques have proved to be less than advantageous. Fletcher et al. (1959) found that analytical difficulties encountered when using their lanolin impregnated pads made the use of this type of monitoring device impracticable. Skin swabbing is a laborious way to monitor dermal exposure. Durham and Wolfe (1962) found that it took 25 strokes with each of four ethanol soaked swabs to remove an average of 91 percent of the total amount of parathion that was deposited on the hands.

Taking into account the advantages and disadvantages of the various monitoring devices listed above, the simple alpha-cellulose and multi-layered gauze pad methods are recommended for monitoring dermal exposure to pesticides. Durham and Wolfe (1962) first described the construction and use of these monitoring devices. Davis (1980) repeated much of this work and included information on validation of methodology and problems encountered during field monitoring. Durham and Wolfe (1962) also reported on the testing of these monitoring devices. They demonstrated the effectiveness of alpha-cellulose pads in reflecting the amount of pesticide deposited on spraymens' forearms. This was accomplished by comparing the residues found on pads to those found on adjacent areas of skin swabbed with ethanol. Unfortunately, they did not carry out a similar study to determine how well multi-layered gauze pads reflect the ability of skin to entrap dry residues. However, they did test the ability of these pads to retain dusty residues. When dust was applied to the surface of these pads, and the pads were inverted and shaken mechanically, approximately 90 percent of the applied dust was retained. Both of these types of pads are easy to construct and use. High quality materials are available for their construction, and if such materials are used, preextraction is usually not necessary. Extraction of residues from both these types of pads is relatively easy to perform and extraction efficiencies are usually very high.

The practicality of alpha-cellulose and multi-layered gauze pads has been demonstrated by their usefulness in collecting field data for over 25 years. Most applicator dermal exposure data were collected using these dosimeters. It is imperative that applicator exposure data collected in the future be at least comparable to the existing data base. If dermal exposure data are to be collected using any other methodology, an appropriate demonstration of the comparability or superiority of that method should be included in the study protocol when it is submitted for review.

2. Monitoring hand exposure

Any brief review of the literature concerning dermal exposure of pesticide applicators will demonstrate the important contribution of hand exposure. To illustrate this, references on hand exposure to workers during various spray operations are shown in Table 1-2.

The exposure of workers' hands to pesticides has been monitored with lightweight absorbent gloves or sections cut from the back and palm of such gloves (Wojeck et al., 1981; Davis et al., 1983a) or by swabbing or rinsing the hands with various solvents in several different ways (Durham and Wolfe, 1962; Ware et al., 1974; Maddy et al., 1980). All of these methods except those that employ absorbent gloves will not remove residues that are absorbed into the skin during the exposure period. However, the use of absorbent gloves may overestimate hand exposure. Even smooth surfaced nylon gloves may retain several times more residue than would have adhered to flesh (Davis et al., 1983a). Since hand exposure is often such a large component of total exposure, the use of gloves may result in a significant overestimation of total dermal exposure.

Gloves also contain foreign materials such as sizing which may be difficult to remove by preextraction and which may interfere with chemical analysis of low levels of residue. Swabbing the hands with solvent is not satisfactory because of difficulties in adequately removing residues from between the fingers and around the fingernails. Durham and Wolfe (1962) found that they could recover approximately twice as much residue from workers' hands by using a bag rinse method rather than swabbing. Washing the hands in a stream of solvent or in a basin containing solvent is probably as effective and faster than shaking the hands in plastic bags containing solvent, but is not as standardized or as convenient as the bag rinse.

A problem with any washing procedure is finding a solvent that will provide adequate removal of residues without causing injury to the skin or increased absorption of a pesticide. For many years, hundreds of contaminated workers' hands have been rinsed with 95 percent ethanol, water, or water containing detergent, without evidence of skin injury or increased absorption of pesticides. However, there have been several instances of problems with degradation of residues or interference with analyses due to the solvent used.

Table 1-2. Contribution of Hand Exposure to Total Potential Dermal Exposure for Pesticide Applicators

Activity	Hand Exposure as % of Total Dermal Exposure	Reference
Drivers of tractors equipped with canopies during air-blast spraying of citrus	41	Wojeck et al., 1982
Bulk spray suppliers for above application	52	Wojeck et al., 1982
Drivers of ordinary tractors during boom spraying of tomatoes	25	Wojeck et al., 1983
Applicators using hand guns to spray aquatic weeds from airboats	47	Wojeck et al., 1983
Drivers for airboats for above application	89	Wojeck et al., 1983
Aerial applicators	55	Maddy et al., 1983
Flaggers for above application	39	Maddy et al., 1983
Applicators spraying lawns, trees, and gardens with power sprayers	37	Leavitt et al., 1982
Applicators spraying lawns with hose-end sprayers	98	Davis et al., 1983b

Most existing hand exposure data were collected using some type of rinsing procedure and it is imperative that any such data collected in the future be comparable to the existing data base. Therefore, it is recommended that exposure of the hands be assessed by washing and the most convenient washing procedure for use in the field is the bag rinse method developed by Durham and Wolfe (1962). Lightweight monitoring gloves have also been routinely used and this technique is also acceptable to the Agency (see Section 230.G). If a registrant elects to employ some other procedure, it will be necessary to obtain prior Agency approval for the data to be acceptable.

3. Additional considerations

After an investigator has determined which monitoring devices and processes are suitable for the exposure situation being studied, there are still several questions that must be answered before monitoring can begin. These are: how many dermal pads are required to assess each exposure and where should these pads be located on the workers; how many replicate exposures are necessary and what constitutes a replicate; what monitoring is necessary when the workers are required to wear protective garments; and how long is an acceptable exposure period? Enough data must be gathered so that the exposure estimates resulting from the study will reflect the range and magnitude of exposure that a typical user of the pesticide will receive. When all the resources necessary for planning, implementing, and completing an exposure study are addressed, extra replicates or extra pad locations should be considered to ensure valid conclusions.

a. Number and location of dermal pads

Most investigators have essentially adopted the number and location of dermal pads used by Durham and Wolfe (1962). They recommended that each worker be monitored with a set of ten pads. The Agency requires the use of at least ten pads attached at the following locations: in front of the legs just below the knees, in front of the thighs, in back of the forearms, on top of the shoulders, in back of the neck at the edge of the collar, and on the upper chest near the jugular notch. Moving these pads to locations other than those specified must be approved by the Agency. However, the investigator is free to include any additional pads he feels are necessary for a better estimation of exposure, e.g. head patches. The relationship of these pads to various areas of the body will be discussed in a following section.

Assuming that the workers' shirts and trousers will be constructed of different materials and that one will want to estimate how much residue will penetrate the clothing, extra pads could be attached under the appropriate clothing. These pads should be placed adjacent to but not covered by one of the outer pads. The locations chosen for these extra pads should be in areas of the body that are expected to receive the highest exposure. Pesticide penetration of clothing will also be discussed in a later section.

If it is suspected that an exposure situation will result in extraordinary exposure to an area of the body that is not well represented by the normal pad locations, pads should be moved or extra pads added to assess such exposure. For example, if a mixer often carries large bags of a dry formulation, the investigator would need to move the forearm pads to the inside of the arms and add an extra pad on the stomach to determine exposure that occurred in these areas due to contact with the outside of bags.

To reduce laboratory work, pads from opposite sides of the body can be combined prior to extraction. However, the back and chest pads cannot be combined, as separate residue values are needed from these pads for calculations. Also, pads from opposite sides of the body should not be combined if one of these pads is to be used in conjunction with an adjacent pad under the clothing to assess penetration.

It is advised that supervisors instruct workers participating in the study to avoid touching the exposure pads. Also, to assist in the documentation of pad placement, some investigators have found it useful to employ photographic records.

b. Monitoring when workers are required to wear protective garments

If the pesticide being studied is, or will be, registered for use only when wearing protective garments, dermal monitoring is slightly different. In addition to the standard external patches, the Agency may require that investigators monitor workers with extra pads under the protective garments to assess penetration. These pads should be located in regions that are expected to receive maximum exposure such as beneath garment seams. Since the maximum exposure or area of penetration cannot always be accurately anticipated, additional pads should be placed under unseamed areas of protective garments in all the same locations as specified for dermal exposure monitoring of workers not wearing protective clothing. Pads under protective garments should be near, but not covered by any pads on the outside of the clothing. Even if the label specifies that protective gloves must be worn, hand exposure under the gloves must be assessed. Maddy et al. (1983) as well as other investigators have clearly demonstrated that workers, even when wearing rubber gloves, can receive significant hand exposure.

c. Acceptable exposure periods

It is difficult to specify in advance the optimal exposure period to monitor. This will depend on the nature of the material being applied and the activity being studied. The ideal period is long enough to collect sufficient residue for analysis but not so long that there is significant loss of residue through evaporation, absorption, or chemical conversion.

Serat et al. (1982) found significant losses of both parathion and dicofol after fortified fabric patches were exposed to ambient conditions for 4 to 6 hours. Their tests included cotton gauze but not alpha-cellulose pads. However, Durham and Wolfe (1962) detected no loss of either parathion or DDT from alpha-cellulose pads compared to worker's forearms, unless the loss occurred at the same rate from both surfaces. They did not specify the exposure period, but usually monitored workers for 30 minutes to 2 hours.

It is also convenient to change monitoring media and perform hand rinses at some natural break in the workers' schedule. The items shown in Table 1-3 will provide some idea of exposure periods that have proved useful for monitoring various activities.

4. Dermal exposure calculations

After the amount of residue on a unit area of exposure pad during a unit time of exposure has been determined, several assumptions are used to estimate the worker's potential dermal exposure. It is necessary to extrapolate the amount of pesticide found on each unit area of pad to the amount that would have impinged on the total body region represented by the pad. This assumes that certain pads represent certain regions of the body and that the surface areas of these regions are known. An assumption would also be made as to how much of the residue found on a pad would have penetrated the worker's clothing.

a. Assumptions concerning the surface area of regions of the body and pad locations that represent these regions

Most of the literature describing pesticide exposure monitoring (Durham and Wolfe, 1962; Wolfe, 1976; and Davis, 1980) has recommended the use of surface areas based on the method of Berkow (1931). Popendorf and Leffingwell (1982) examined the surface area values that several investigators

Table 1-3. Exposure Periods from Selected Pesticide Exposure Monitoring Studies

Activity	Exposure Period	Reference
Ground-sprayer application	30 to 120 min	Maddy et al., 1980
Mixing/loading for above application	10 to 30 min	
Pilots for aerial application	1 to 10 hrs	Peoples et al., 1979
Mixing/loading for above application	1 to 10 hrs	
Flagging for above application	1 to 7 hrs	
Application to crawl spaces or around slab foundations for termite control	1 1/2 to 2 hrs	Maddy et al., 1979
Tractor drawn low-pressure boom sprayers	2 hrs	Davis, 1980
Backpack type hand sprayers	3 to 4 hrs	Davis, 1980
Application to lawns and shrubs with compressed air or hose-end sprayers	15 to 30 min	Davis et al., 1983b
Air blast application to orchards	20 min to 2 hrs	Wolfe et al., 1972

proposed for various regions of the human body. They concluded that extrapolating exposure from the pad to the body region using Berkow's method is inappropriate because Berkow specifically adjusted body region surface areas for their relative importance to burn victims. Popendorf and Leffingwell (1982) developed regional surface areas based on anatomic modeling of the 50th percentile man.

The Exposure Assessment Group/Office of Health and Environmental Assessment (OHEA) (EPA, 1985b) investigated previous research on the surface area of body regions. Based on this review, the model $SAP = a_0W^{a1}H^{a2}$ (where SAP is body part surface area in m2, W is body weight in kilograms, H is height in cm, and a_0, a_1, and a_2 are constants for each body region) was developed and compared to data collected from the Second National Health and Nutrition Examination Study (NHANES II). The coefficient of determination for adult males was greater than 0.7 for all body regions with the exception of the head, upper arms, hands and feet. Foot exposure is rarely measured, and hand exposure is measured directly using hand rinses or cotton gloves.

Table 1-4 shows the surface area estimates presented by Berkow and those derived from the OHEA report. A comparison of the two sets of estimates shows close agreement for the trunk area, forearms, and lower legs. The OHEA estimates for upper arm and thigh surface areas are substantially greater than the Berkow estimates.

The Agency recommends that the surface areas presented in Table 1-5 be used in calculating exposure to body regions. For consistency with past practices and in recognition that the Berkow and OHEA estimates closely agree, the Berkow estimates have been retained with the exception of the upper arms and thighs. The OHEA estimates for the thighs and upper arms have replaced the Berkow estimates.

Davis (1980) suggested that certain exposure pads be used to represent various regions of the body. However, his representation of vertical facial areas by horizontal shoulder pads may well lead to the overestimation of facial exposure. Therefore, it is recommended that future exposure studies employ the pad locations shown in Table 1-5 for extrapolation from residues found on dermal pads to exposure estimates for adjacent regions of the body.

b. Penetration of residues through clothing

The problem of accounting for protection from exposure by a worker's clothing is not easily dealt with because of the scarcity of appropriate data. Assumptions ranging from

Table 1-4. Surface Areas for Regions of the Adult Male Body

Region of the Body	Surface Area (cm2) of Region (Berkow)	Surface Area (cm2) of Region (OHEA)a
Head	----	1300
Face	650	----
Trunkb	----	7390
Back of Neck	110	----
Front of Neck	150	----
Chest/Stomach	3550	----
Back	3550	----
Upper Arms	1320	2910
Forearms	1210	1310
Hands	820	990
Thighs	2250	3820
Lower Legs	2380	2560
Feet	----	1310

a For 50th percentile man (NHANES II, EPA 1985b)

b Includes the neck

Table 1-5. Surface Areas for Regions of the Adult Body and Locations of Dermal Exposure Pads that Represent These Regions

Region of the Body	Surface Area (cm2) of Region	Location of Pad(s) Representing Region
Head	1300[a]	Shoulder, Back, Chest[b]
Face	650	Chest
Back of Neck	110	Back
Front of Neck[c]	150	Chest
Chest/Stomach	3550	Chest
Back	3550	Back
Upper Arm	2910	Shoulder and Forearm/ Upper Arm
Forearm	1210	Forearm
Hand	820	---
Thigh	3820	Thigh
Lower Leg	2380	Shin
Feet	1310	---

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[a] Surface area for the head includes the 650 cm2 face surface area

[b] Exposure to the head may be estimated by using the mean of the shoulder, back and chest patches or by using a head patch.

[c] Includes "V" of the chest.

complete protection of covered areas (Durham and Wolfe, 1962) to complete lack of protection (Wojeck et al., 1983) have been used to circumvent this problem. Maddy et al., (1983) monitored a total of 102 individual exposure situations of mixers, loaders, flaggers, and applicators. They found that an average of approximately 23 percent of total dermal exposure was due to residue that penetrated seven-ounce, 65 percent Dacron polyester, 35 percent cotton twill coveralls. Gold et al. (1982) studied the exposure of 38 urban applicators and found that the mean penetration of carbaryl through clothing was only 6.1 percent. Their data appeared to indicate that penetration was not greatly affected by formulation (2.4% to 11% penetrated), crop (2.3% to 11% penetrated), or type of application equipment used (4.7% to 16% penetrated). The same group of investigators (Leavitt et al., 1982) also studied the penetration of carbaryl to the skin of five professional applicators wearing jumpsuits with open collars and short sleeves of unspecified material. The workers used power sprayers to treat trees and their exposure resulted from mixing, applying and equipment cleaning. An average of 5 percent of the material that contacted their clothing penetrated to the skin. Although the mean values of total pesticide contacting the different regions being monitored ranged from 0.84 to 13 ug/cm ^{2}/hr, the average amounts that penetrated ranged from 3.4 percent to 6.9 percent. Spear et al. (1977) and Popendorf et al. (1979) reported that up to approximately 50 percent of pesticide residues impinging on the clothing of fruit harvesters would have penetrated to the skin. Freed et al. (1980) found that up to approximately 50 percent of the active ingredient from simulated sprays penetrated a 65 percent polyester, 35 percent cotton fabric, but that 100 percent cotton fabric was much more resistant to penetration.

Because existing data indicate such extreme variability in permeation and/or penetration of clothing (including protective) by pesticides, study investigators should consider laboratory testing procedures to supplement field studies in some cases. The Agency believes that laboratory testing of a variety of protective clothing materials would provide additional valuable data, since it is unrealistic to assume that all users of a particular pesticide product would wear exactly the same type of protective clothing. Registrants are encouraged to discuss study design involving protective clothing or equipment performance with Agency personnel before submitting protocols for approval.

B. Respiratory exposure monitoring

When equipment used for monitoring respiratory exposure during the application of pesticide sprays has been properly designed, it is found that respiratory exposure is usually a very small component of total exposure. This is demonstrated by the first five exposures shown in Table 1-6. Assuming that 100 percent of the material that is potentially available for respiratory exposure is absorbed, a situation is rarely found where the respired dose would be a significant portion of the total dose received during normal spray operations. However, as illustrated by the last two lines of Table 1-6, there are situations when respiratory exposure can be significant. These situations usually involve the application of dusts, aerosols, and fumigants or the application of sprays in enclosed spaces. Also, as the dermal penetration of the pesticide decreases, the relative importance of the inhalation route becomes greater.

In view of the preceding, registrants may not be required to monitor for respiratory exposure unless the Agency has reason to believe that such exposure would be significant. However, respiratory exposure monitoring will be required if the material in question has been demonstrated to cause an adverse biological effect that is associated with or accentuated by respiratory exposure; if the formulation or application method is expected to result in significant respiratory exposure; or if the formulation or application method has an unknown potential for respiratory exposure.

No single methodology can be specified as best for respiratory exposure monitoring in all cases. The method of choice will depend on the chemical and physical nature of the material being studied and may also depend on the activity being monitored. An extremely wide variety of methods are available. Investigators concerned with such monitoring are referred to the following extensive reviews. The methodology used for personal air monitoring was reviewed by Linch (1974). However, he did not emphasize sampling media that are most useful for the collection of pesticides. Van Dyk and Visweswariah (1975), on the other hand, reviewed the various media available for collection of pesticides but with major emphasis on high volume sampling. One of the latest and most complete reviews of all methodology used for field monitoring of airborne pesticides was by Lewis (1976). Other sources of information that will be of help in planning and implementing studies of respiratory exposure to pesticides are the protocol by Lewis et al. (1980) and articles by Durham and Wolfe (1962) and Davis (1980).

1. Personal monitoring of respiratory exposure

These guidelines require that potential exposure by the inhalation route be estimated using personal monitors. Several techniques are available to the investigator. These range from simple gauze pads used in place of dust

Table 1-6. Contribution of Respiratory Exposure to Total Potential Exposure for Pesticide Applicators

Activity	Physical Form of Pesticide Used	Respiratory Exposure as % of Total Exposure	Reference
Drivers of tractors equipped with canopies during air-blast spraying of citrus	Spray	0.029	Wojeck et al., 1982
Bulk spray suppliers for above application	Unspecified	0.004	Wojeck et al., 1982
Drivers of ordinary tractors during boom spraying of tomatoes	Spray	0.04	Wojeck et al., 1983
Applicators using hand guns to spray aquatic weeds from airboat	Spray	*N.D.	Wojeck et al., 1983
Drivers of airboats for above application	Spray	*N.D.	Wojeck et al., 1983
Applicators using aerosol generator for mosquito control	Aerosol	9.1	Culver et al., 1956
Applicators using hand knapsack mister for spraying tomatoes	Mist	3.1	Simpson and Beck, 1965

*None Detectable

filters in modified respirators to rather exotic solid sorbents used with battery-powered personal air samplers. The various media and pumping systems that may be applicable have been reviewed by Linch (1974) and by Lewis (1976).

The gauze pad procedure (Durham and Wolfe, 1962) is convenient because it is simple to construct the necessary pads and to modify the respirators, and exposed pads can usually be extracted in the same manner as exposed dermal pads. Also, the test subject produces the air flow for trapping so that breathing rate and total volume inhaled do not have to be estimated separately. However, the investigator must ensure that the respirator pads are an efficient trap for the material under study, that the respirator is well fitted to the test subject's face, and that the subject does not remove the mask during the exposure period. Construction of respirator pads, details of respirator modification, and a description of field operations used with this procedure follow in Sections 230(J) and (K).

In the past, the second most commonly employed procedure for assessing respiratory exposure to pesticides under field conditions utilized ethylene glycol as a sampling medium. The use of this material in midget impingers presents some problems for personal monitoring since the liquid is easily spilled as a worker goes about his duties and the liquid may also be drawn into the pump mechanism. These problems may be alleviated by using the "spill-proof" microimpingers described by Linch (1974). Even with spills eliminated, this procedure, as with all procedures employing a mechanical pump, requires an estimation of a worker's ventilation rate. This varies with the amount of exertion employed. Another problem that may be encountered with this system is loss of residue. Some materials are not trapped by ethylene glycol or are rapidly lost from solution during prolonged sampling. Other materials are degraded in ethylene glycol, probably by hydrolysis since the ethylene glycol also traps considerable moisture from the air.

The use of solid sorbents for personal monitoring of pesticide exposure is gaining in popularity and this technology is developing rapidly. The major disadvantage of using sorbents, in addition to the need to estimate the worker's ventilation rates, is the restriction of airflow by finely divided particles. Another drawback is degradation or chemical conversion of some pesticides bound to active sorbents. A description of the use of personal monitoring pumps and samplers follows in Sections 230(I) and (K).

2. High volume air sampling

In atypical cases where levels of toxicants in the air are too low to be sampled by personal monitors or where suitable monitoring media are not available, investigators may have to resort to the use of high volume samplers. The use of such samplers has been described in a number of other publications (Lewis 1976; Lewis et al., 1980; and Van Dyk and Visweswariah, 1975). These are not generally recommended for monitoring occupational exposure in the field unless absolutely necessary. For this reason they will not be detailed further in these guidelines.

C. Dermal and respiratory exposure monitoring at indoor sites

In general, monitoring of exposure during application of pesticides at indoor sites involves the same considerations as monitoring during outdoor applications. Even though some of the types of sprayers used for indoor applications may produce aerosols with a greater potential for respiratory exposure than is generally found for outdoor applications, monitoring methods that are satisfactory for outdoor applications should also be satisfactory for indoor sites.

It has been estimated that pesticides are used in more than 80% of U.S. households (EPA, 1980a). This fact and several others lead to the special concern one must have for the exposure of individuals occupying dwellings that have been treated with pesticides. Firstly, indoor residues can persist for significantly greater periods of time compared to similarly applied outdoor residues (Davis et al., 1977). This increased indoor persistence may be due to an environment that protects residues from sunlight and moisture, provides for different degradation pathways, and inhibits their dissipation by limiting ventilation of vapors. Secondly, since modern construction methods have produced dwellings that are energy efficient and greatly restrict air exchange, they may exacerbate problems with indoor air pollution (Spengler and Sexton, 1983).

As was mentioned above, it is recommended that the dermal and respiratory exposure of applicators be monitored using the same methodology that is recommended for outdoor applications. However, since more respiratory exposure to aerosols and vapors is expected, the investigator should ensure that the trapping medium used to assess this exposure is particularly efficient in trapping these forms.

For post-application respiratory exposure monitoring, a battery operated pump fitted with a trapping medium that is an efficient trap for vapors may also be used. However, the sampler need not be worn by a test subject, but only placed at breathing level in the room. Since concentrations of pesticide vapors may be low after application, the investigator may have to sample for extended periods to collect enough material for analysis.

Although one can determine the post-application levels of residues on surfaces by swabbing or by the analysis of material on collection surfaces such as mylar squares that are left in a room for various periods of time after application, the Agency does not feel that any satisfactory system has yet been devised and sufficiently tested to ensure that it will reliably allow one to relate such residues to the potential for dermal exposure. Therefore, surface residue monitoring is not required. Post-application monitoring for estimation of potential dermal exposure will be required, using the same technique as for monitoring dermal exposure to applicators, only on a case by case basis and will depend on the type of pesticide product and its use.

Since the potential for post-application respiratory exposure will be dependent on the nature of the pesticide product used, the sampling schedule for post-application respiratory exposure monitoring will have to be determined in consultation with Agency scientists. This sampling schedule will be created such that the pattern of decline of potential respiratory exposure as a function of time can be defined.

§VI. The Use of Surrogate Data and the Development of Generic Predictive Correlations

Many difficulties and variables associated with carrying out exposure monitoring studies in the field during actual application have been discussed previously in this document. Many of the variables, such as climatic conditions and the degree of care exercised by individuals, are not under the control of the scientist supervising the study. These uncontrolled variables usually result in a wide variation in experimental results. The amount of resources required to do field studies for every controllable variable (such as crop, application method, or pesticide) would be very high. For these reasons, and for the scientific reasons discussed below, the Agency policy (EPA, 1980b; Reinert and Severn, 1985) is to use "surrogate" data to estimate applicator exposure when appropriate.

"Surrogate" or "generic" exposure data are defined herein as exposure monitoring data collected for other pesticide chemicals applied using comparable methods and under similar conditions as for the pesticide under assessment. The mechanics of the use of surrogate data have been discussed in detail in public fora and in the published scientific literature in recent years (Severn, 1982; Hackathorn and Eberhart, 1985; Honeycutt, 1985; Reinert and Severn, 1985). The assumption in the use of surrogate data is that in many application scenarios, the physical parameters of application, not the chemical properties of the pesticide, are most important in determining the level of exposure. Note that when using a passive dosimetry monitoring method, what is measured is the amount of chemical impinging on the skin surface, or available for inhalation, not the actual dose received. Factors such as dermal penetration are, of course, expected to be highly chemical-dependent. A review of all available information on pesticide exposure during application activities, as discussed earlier, supports the use of surrogate data for applicator exposure assessments.

There is general agreement that the principal application parameter that determines the level of exposure is the method of application. One application technique for which there is a great deal of exposure monitoring data is ground application to orchards using high pressure or airblast equipment. The Agency has evaluated these exposure data to attempt to derive statistically valid and useful predictive correlations. A significant correlation was found between application rate and dermal exposure. A Spearman Rank Correlation Analysis (Snedecor and Cochran, 1980), a test to determine if an increase in exposure is associated with an increase in application rate, indicated a statistically significant correlation. A less significant correlation was found for another application parameter, tank concentration.

A linear regression analysis of dermal exposure and application rate also indicated a significant correlation (Figure 1-2). The actual data points shown are the mean values observed in each study and are not weighted for the number of replicates in that study. Weighted values were used properly to generate the regression line and the 95 percent confidence limits are shown with dotted lines. These dermal exposure values are normalized to 3,000 cm^2 of exposed skin, corresponding to an applicator wearing long pants, a short-sleeved open necked shirt and no gloves or facial protection. The correlation is quite remarkable ($r=0.7$) considering that all other application, climatic, and equipment factors are contained under this umbrella of uncertainty.

The above is an example of a correlation developed using the generic approach. The data used were taken from studies on a variety of pesticides in which over two thousand separate measurements of potential dermal exposure were made. This correlation allows the Agency to estimate exposure for the airblast application of other pesticides with a certain level of confidence. As new data are made available for this application technique, this correlation will be updated to reflect these additional data.

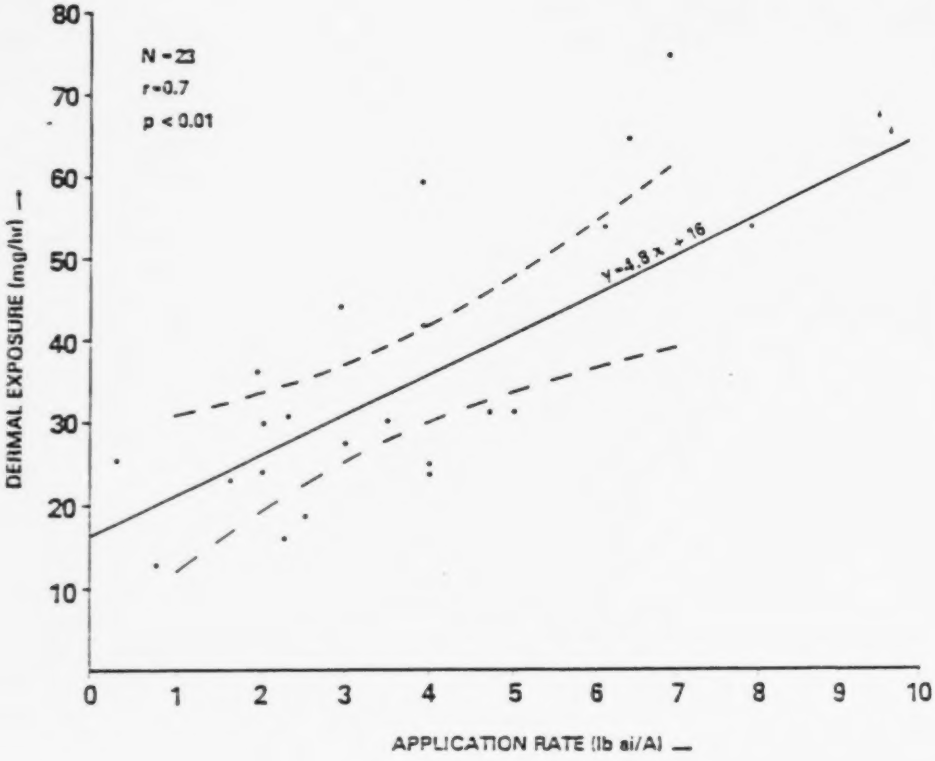

Figure 1-2.

Correlation of Dermal Exposure and Application Rate for Orchard Spraying Using Airblast Equipment

The data points shown are the mean values from the studies. The regression line and 95 percent confidence limits (dotted lines) were generated using means weighted for the number of replicates in each study. Exposure is normalized for 3,000 cm^2 of exposed skin area.

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All of the studies included in the airblast data base are from published or publicly available sources. The results of studies carried out by registrants according to these guidelines, like any other data generated in support of a registration application or continued registration, may be considered proprietary, or involve data compensation matters, and are not currently used as part of a generic data base. A proposal has been put forward, however, to accomodate the routine use of registrant-generated exposure data on a generic basis so that the overall data base for estimating applicator exposure would be significantly expanded (Hackathorn and Eberhart, 1985). The National Agricultural Chemicals Association and the Agency are pursuing actively this proposal.

The development of a generic data base and valid predictive correlations where possible, is a procedure which the Agency will continue to pursue. The Agency believes that it is more reliable to estimate exposure based on an extensive, scientifically sound and appropriate data base rather than from the results of an individual study with a limited number of replicates, even if that single study is judged valid by the Agency. As the Agency receives additional valid exposure data from any source, the data will be added to the existing data base, thus expanding that data base and improving its reliability for estimating exposure for other pesticides.

Laboratory and Field Monitoring Methodology

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The Organization of Sections 230 through 236

These guidelines are divided into six sections. Section 230 contains the information, test standards and language common to all the remaining sections. Section 231 and 233 address potential dermal exposure during application at outdoor and indoor sites respectively. Sections 232 and 234 parallel 231 and 233 for potential inhalation exposure. The indoor sections address exposure both during and after application. Section 235 reviews the requirements for estimating exposure using biological monitoring. Section 236 provides instructions for reporting data.

§230 General Information and Exposure Methodology Common to Sections 231 through 236

The studies carried out according to these guidelines will be acceptable to the Environmental Protection Agency, but investigators may find additional helpful information in several other publications. These are Davis (1980), Durham and Wolfe (1962), Lewis et al. (1980), and Wolfe (1976). The article by Davis should be particularly helpful because it was written as a primer for those who have never conducted an exposure study. It contains many practical tips about field operations.

It cannot be overemphasized that investigations carried out according to these guidelines must be properly designed to provide for maximum protection of the study subject's health. Studies conducted to obtain human exposure data must not violate Section 12(a)(2)(P) of FIFRA. Informed consent should be obtained in writing from all subjects who will be exposed as a result of these studies, and proposed protocols may need to be approved by the appropriate human studies committee for the state in which the exposure will occur. Also, Guidelines for the Protection of Human Subjects of the Department of Health and Human Services should be considered for the design of such studies (Health and Human Services, 1981).

Proper administration is vital for successful exposure monitoring studies, as well as to ensure the safety of the workers being studied. It is most important that field studies have professional supervision by persons who are knowledgeable and experienced in exposure assessment. Investigators who are inexperienced are strongly urged to arrange to accompany an experienced investigator during an entire exposure study before attempting a study on their own.

All conditions specified on the label for legal application of registered pesticides must be observed. Existing or proposed labels with inappropriate information concerning protective clothing will be addressed on a case by case basis as protocols are submitted. Chemical resistant gloves, NIOSH approved respirators, or any other protective gear that is required, must not be removed during the exposure monitoring period. Also, any protective clothing and equipment required for the workers must not be altered in any manner that would result in decreased protection.

Studies must be designed so that an exposure is measured separately for each activity associated with an application even when, in actual practice, an individual is involved in more than one activity. For example, separate estimates shall be made for the exposure received during mixing/loading the pesticide and while driving the tractor that pulls the ground boom sprayer. Any differences in the magnitude of exposure for these two activities may be addressed by different regulatory options. The Agency recognizes, however, that for certain atypical application scenarios, it would be impractical to measure exposure for each work activity. In such scenarios, monitoring of combined activities will be allowed on a case by case basis.

Tests must be carried out at label application rates using the actual formulation and packaging that will be commercially available. The EPA may require the estimation of exposure to active ingredient(s); inerts or contaminants; any other chemicals present in the formulation; any degradation or transformation product(s), or any combination thereof. Also, all data must be collected and documented in accordance with applicable sections of the most current EPA Pesticide Program's Good Laboratory Practice Standards (EPA, 1983), and presented as described in Section 236.

Investigators must exercise care to ensure that all operations contributing to the exposure under investigation are carried out in a manner that is consistent with typical use. Outside applications must be performed under weather conditions (e.g. wind speed) that are consistent with label restrictions or that are generally recognized as acceptable for spraying. Registrants must submit proposed exposure study protocols to the EPA for review and receive Agency approval prior to initiating the study.

The type and completeness of exposure data required by the EPA will depend on the toxicity of the chemicals involved; the proposed uses for the formulation; the proposed methods of application, and the availability of data from studies using similar formulations and application methods. Complete studies will not be required for every product being registered, and the need for new data is expected to decrease as the exposure data base increases. Exposure data may be required for any method of application proposed by the registrant.

It is impossible to specify a particular duration of exposure that would give satisfactory results for a given operation. The exposure period must be long enough to collect measurable residues, if exposure is occurring, but short enough to avoid excessive losses due to volatilization or decomposition (see Table 1-3 for examples of exposure periods that have proved useful for monitoring various activities).

The Agency requires that each exposure situation be evaluated using at least fifteen replicates. Each replicate is a measure of the exposure to one worker for one exposure period. To obtain a single "typical" exposure for the situation being studied, one must include individual values obtained under as many different conditions that are expected to significantly affect exposure as possible. Three variables that are expected to have the most significant effect on exposure are differences in application equipment, wind conditions during outdoor applications, and most importantly, different work practices and attitudes toward safety of the study subjects. Therefore, to obtain a reasonable cross section of the variation of individual exposure values, the Agency requires that the fifteen replicates be obtained from a minimum of five replicates from each of a minimum of three application sites. However, it is recommended that the replicates be obtained using as many different workers as possible. Fewer replicates will be acceptable under special circumstances. For example, when applying an experimental pesticide by air, where the availability of subjects is limited, a minimum of nine replicates obtained from three replicates each at a minimum of three sites will be sufficient.

Many of the supplies and equipment described in these guidelines will be followed by a trade name and/or suggested source. This is meant as a guide to assist locating supplies, constructing dosimeters, or to describe methods that have been effective in the past. Any mention of trade names or commercial products does not constitute endorsement by the Agency and does not imply that only those items or methodologies are acceptable. Investigators are encouraged to develop new methods for measuring exposure that may prove more effective than those described.

ESTIMATION OF DERMAL EXPOSURE BY PASSIVE DOSIMETRY

A. Construction of dermal exposure pads and storage envelopes for exposed pads

1. Dermal exposure pads for sprays

Pads to be used for estimating dermal exposure to sprays are to be constructed from papermaking pulp or a similar material, approximately 1 mm thick. Hereafter this material will be referred to as alpha-cellulose. A good grade of alpha-cellulose will absorb a considerable amount of spray without disintegrating. Further, it should not typically require preextraction to remove substances that interfere with residue analysis. This should be determined before exposure tests using such pads begin. Acetanier P-FA produced by ITT Rayonier, Incorporated, Chemical

Cellulose Sales Department, 1177 Summer Street, Stamford, Connecticut, 06904, has been found to be satisfactory for this use. It is available only in 500 pound bales, but 4 pound samples of 10 inch square sheets are available for free (shipping not included) if an investigator wishes to compare it to other potential dermal dosimeter materials before choosing an appropriate pad material.

Another material, which is satisfactory and more readily available in small lots, is preparative chromatography paper (17 Chrom) available in sheets from Whatman, Incorporated, 9 Bridewell Place, Clifton, New Jersey, 07014. The large sheets available from the manufacturer are cut into approximately 4 inch (10.2 cm) squares which are then stapled to a protective backing of glassine paper or aluminum foil. Glassine powder-weighing paper precut into 4 inch (10.2 cm) squares is produced by Schleicher and Schuell, Incorporated, and is available through most laboratory supply companies. The glassine paper or aluminum foil backing prevents contamination of the exposure pad by material deposited on the subject's clothing during a previous spraying.

2. Dermal exposure pads for dry residues

Pads to be used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulations, are to be constructed from layers of surgical gauze. A piece of heavy filter paper backing approximately 4 inches (10.2 cm) square is overlayed with approximately 32 plies of surgical gauze and the components are bound together with masking tape along all four edges. The finished pad should be bound so that an area of gauze at least 2.5 inches (6.4 cm) square is left exposed. The gauze must be checked for material that would interfere with analysis and be preextracted if necessary.

For the backing material used in the construction of gauze pads, a white crepe filter paper available from VWR Scientific (VWR Grade No. 617) has been found to be satisfactory. This paper is available in 20 inch (50.8 cm) square sheets. The gauze is available from several medical supply companies as 4 inch (10.2 cm) square gauze surgical sponges.

3. Storage envelopes to contain exposed pads

If exposed pads are to be stored prior to extraction, envelopes cut from heavy filter paper may be used. The same white crepe filter paper that is used for backing the dust exposure pads is suitable for this use. It is also necessary to check the envelopes for material that will interfere with analysis, since that portion of the envelope that will be in contact with a stored exposure pad must also be extracted to obtain any residues that may have been transferred from the pad. A 5 inch (12.6 cm) by 10-inch (25.2 cm) rectangle cut from the large sheet of filter paper is folded once across the long dimension so that approximately 3/4 inch (2.2 cm) of the lower portion projects above the upper portion. This projection provides a convenient space to record the sample number of the exposed pad contained in the envelope.

The filter paper envelopes are contained in individual unwaxed sandwich bags approximately 6.5 inches by 8 inches by 1 inch (16.5 cm x 20.3 cm x 2.5 cm). The sandwich bags keep the exposed pads within the protective envelopes and help protect against contamination.

B. Preparation of hand rinses

Hand rinses are prepared with solvent contained in freezer bags or other plastic bags strong enough to withstand vigorous shaking. A satisfactory bag is designed to contain 1/2 gallon (1.9 L) of frozen food. Bags less than 1 mil (0.025 mm) in thickness will puncture too easily to be useful. Use the heaviest available material that is still pliable enough to be wrapped in a tight seal around the wrist.

During preliminary studies, plastic bags must be shaken with the solvent to be used for field studies to ensure that material which may interfere with analysis is not present. This procedure must be followed regardless of the type of bag used.

Ethanol (95 percent) has been found to be satisfactory for the removal of most pesticide residues without undue damage to the skin. If the material under study is unstable or insoluble in ethanol, it may be necessary to remove residues using a detergent solution rinse followed by partition of the residue into a suitable solvent for analysis.

Alcohol hand rinses are prepared by placing 200 ml of 95 percent ethanol in a freezer bag, performing the hand rinse, placing the bag in a wide-mouth 1-pint Mason jar, twisting the top of the bag shut to contain the solvent, and sealing the jar with a lid and ring. A sheet of aluminum foil inside the lid will help to prevent contamination of the sample. A piece of masking tape on the outside of the lid provides a convenient space to record the sample number of the hand rinse. The sample bottles and caps should be labeled to avoid mix-ups. Stainless steel or other appropriate containers may be substituted for mason jars.

C. Laboratory studies necessary before field studies are initiated

The total recovery from field fortified samples must be at least 50 percent. Field fortified samples should reflect the total sample monitoring and analysis process. Applicable Good Laboratory Practices (EPA, 1983, or the most current edition) must be followed at all times.

1. Analytical procedure

The specific analytical procedure to be used will depend on the material being studied. The procedure chosen must be capable of quantitative detection of residues on exposure pads at a level of 1 ug per cm2 (less if the dermal toxicity of the material under study warrants a greater sensitivity).

2. Stability of the compound of interest on damp stored pads

Two options will be offered below under "Field Operations" (Section 230(D)2) as to how exposed pads used with sprays may be handled prior to extraction. If the investigator elects to store exposed pads pending extraction, then a study must be documented for the stability of the material on moist exposure pads.

Exposure pads are to be fortified with a pesticide product diluted to use concentration, at approximately the levels that are expected to impinge on pads during field studies. The same formulated pesticide product which will be used in the field study must be used as spray material for pad fortification. The pads and their protective envelopes are to be extracted and analyzed by the methods that will be employed for field studies. The time periods for storage of fortified pads shall be chosen so that the longest corresponds to the longest projected storage period for field samples. A decay curve can then be constructed which will allow extrapolation of residue levels found in field samples back to the time of collection. Results from this study can also be used to determine the length of storage which will be acceptable for the pesticide formulation to be monitored in the field study.

3. Efficiency of extraction

The method chosen by the investigator to extract residues from exposure media must be studied for efficiency of extraction and this study must also be documented. The appropriate type of exposure media must be fortified with simulated spray solution prepared using the same formulation that will be studied in the field and at approximately the same levels as are expected for field samples. The mean ± the standard deviation for recovery shall be determined. If the lower limit of the 95 percent confidence interval is less than 70 percent, then the extraction procedure is unsatisfactory unless approved by the Agency prior to commencing the study. At a minimum, seven determinations should be made to calculate the mean and standard deviation for recovery for each fortification level tested. Studies should always be designed so that extraction efficiencies are the highest possible.

If hand rinses are to be carried out using a particular solvent with subsequent partition into a second solvent for analysis, then a similar study as described above shall be carried out to determine the efficiency of extraction. The same criteria for acceptability also applies to hand rinse extractions.

4. Stability of extracts

If exposure media extracts and hand rinses are to be stored prior to analysis, then a documented study of stability shall be conducted for each different solvent employed. Each solvent shall be fortified with levels of authentic concentrates of the same formulation that will be used in the field studies, and at approximately the same concentration that is expected in extracts from field studies. Each sample should be analyzed immediately before and several times during storage under the conditions to be used for storing extracts from field samples. The periods of storage shall be chosen so that the longest corresponds to the longest projected storage period for extracts from field samples. A decay curve which will allow extrapolation of residue levels found in any stored extract back to the time of extraction can then be constructed and can be used to determine storage conditions for the study to meet total recovery criteria.

5. Estimation of expected stability during the monitoring study

If the stability of the material of interest is unknown, or if the material is volatile or subject to degradation, the investigator must document a study to ascertain loss while pads are worn to determine the length of the monitoring period and to allow for correction for residues lost from collection devices during the monitoring period. No standard procedure has been developed for this type of study, so it will be left to the investigator to develop his own.

It is recommended that collection devices be fortified with simulated spray solution or dust, depending on the material being studied, at approximately the same levels expected to occur during field studies. These dosimeters should then be exposed to weather conditions similar to those expected during field studies and for the same period of time as will be employed in the field.

D. Field operations

1. Attachment of exposure pads

Pads shall be attached, according to the exposure situation, so as to collect residues representative of those impinging on all regions of the body. Normally, a complete set of pads for each exposure period will consist of ten to twelve pads (see Section V(A)3).

The pads are attached to the outside of a worker's clothing or skin at the following locations: top of the shoulders, in back of the neck just below the lower edge of the collar, on the upper chest near the jugular notch; in back of the forearms, and in front of the thighs and lower legs. If the workers are engaged in some activity that is likely to result in extraordinary exposure to regions of the body that are not well represented by the usual pad locations, extra pads must be included to assess such exposure.

If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Since workers often wear upper and lower outer garments made from different types of cloth, pads should also be attached under both garments, particularly, in regions expected to receive maximum exposure. Care must be taken to ensure that any pads under clothing are near, but not covered by, pads on the outside of the clothing.

If the proposed label specifies that the pesticide can only be used by workers wearing protective garments, place the pads where it is possible to assess exposure to unprotected regions. For example, if the workers are wearing full protective suits, pads would be needed on the outside of the garments at the back, chest, and shoulders to assess facial, head, and neck exposure. Additional pads will be necessary under the protective suit at all the previously specified locations to assess penetration. Inside pads must be centered under seams as well as under unseamed material, since seams are often areas of maximum penetration. Registrants are encouraged to discuss exposure studies involving protective clothing with Agency personnel when developing a protocol and before submittal for approval.

Pads may be attached to the skin or clothing by using strips of masking tape along two edges of a pad. Some investigators have utilized specially designed harnesses or lightweight vests fitted with open-fronted pockets to hold the shoulder, chest, and back pads. Others have simply attached the pads to clothing with safety pins. These alternative attachment methods and others have been used successfully and are acceptable.

2. Removal and handling of exposed pads

The procedure for handling exposed pads will depend on the stability of the material being studied. If the laboratory study described in Section 230(C)2 indicates that the material is stable on moist exposure pads, then method (a) described below may be used. This method is advantageous since it requires less time-consuming manipulation of the exposed pads in the field. If the material is found to be unstable or if the investigator elects not to perform the stability testing with moist pads, then method (b) shall be employed. Method (b) may also be employed by choice.

a. Stable residues

Remove the tape used to attach the pad to the test subject and also remove the protective backing from the pad. Slide the prelabeled protective envelope just far enough out of the sandwich bag to insert the pad, then carefully put it back in the bag. Staple all bags containing exposed pads from one exposure of a single test subject together without puncturing the area of the bag containing the samples and store in a chest containing ice or an appropriate plastic gel. Refrigerate the bags until reaching the laboratory.

b. Unstable residues

Remove the tape used to attach the pad to the test subject. Place a template of a convenient size (25 cm2 has been employed with success) in the center of the pad and trim away the excess material around the template. Discard the protective backing and place the sample obtained from the center of the pad in a wide-mouth jar or other appropriate container filled with a convenient volume of a suitable solvent from Section C.4. Store this sample in the same manner as the pads in method (a).

3. Hand rinses

A double hand rinse shall be performed on each hand. These rinses must be done even on workers who wore protective gloves. A plastic bag containing the appropriate solvent is removed from its Mason jar or other appropriate container and is tightly applied just below the wrist bone. The hand is shaken vigorously in the solvent, allowed to drain into the bag for a few seconds, then the bag is returned to its container. This procedure is repeated on the same hand with a fresh bag of solvent before repeating the process on the other hand. These rinses should also be stored under the conditions used for exposed pads until reaching the laboratory.

4. Field fortified samples and blanks

The inclusion of field fortified samples in a study is vital because it will allow data to be corrected for any residue losses that may occur during the exposure period, during storage in the field, and during transportation to the laboratory. Also, if field fortified samples are extracted on the same day as are actual samples that were obtained on the same day, they eliminate the requirement for a study of the stability of residues on damp stored pads (Section 230 (C)2).

A standard procedure to assess losses from field fortified samples has not been developed, so it will be left to the investigator to propose such a procedure. However, the Agency recommends the following as a guide.

Pads should be fortified at approximately the levels expected for actual exposure samples. The fortified pads should then be exposed to the weather concurrently with the pads being worn by the workers. A member of the monitoring team who is careful to position himself where inadvertent exposure cannot occur may wear the fortified pads, or they may be placed in a fixed location that is upwind and a sufficient distance from the application site to avoid contamination. However, investigators are cautioned that upwind locations can quickly become downwind locations and such occurrences will ruin a set of fortified samples.

There should be at least one field fortified sample per worker per monitoring period for each fortification level. These samples should be stored and analyzed along with the exposure samples. Field blanks of exposure collection media such as pads are also required in order to account for any possible contamination which may occur while collecting, transporting, or handling field samples prior to extraction in the laboratory. Field blanks should be handled the same as exposed pads.

5. Field data collection

The type of field data that must be reported will vary with the operation being studied. A set of data shall be compiled for each set of exposure pads and hand rinses. These data shall be indexed so that they can easily be related to any particular exposure value. Two examples of the type of data needed in a particular exposure situation are presented as a general guide as follows. Forms which can be adapted for use in recording these data in the field are shown in Appendix A. Refer to Section 236 for complete data reporting requirements.

E. Laboratory operations subsequent to exposure

As soon as the investigator returns to the laboratory from the field, all samples held in ice chests must be stored in a freezer pending further treatment. A sample history sheet shall be prepared to document laboratory operations. A convenient sheet of this type contains columns labeled: sample number, date sample was collected, date of extraction, date of analysis, and the name(s) of the responsible individual(s) for each laboratory procedure. The lower portion of the sheet contains spaces for recording the conditions of storage for pads and extracts, the extraction procedure employed, and the analytical procedure used. A suggested form for a sample history sheet is shown in Appendix B.

1. Extraction of residues from exposed pads

If exposed pads are returned to the laboratory intact, portions of the pads along with their protective envelopes are cut out as described under Section 230(D)2b. These samples are then extracted according to the procedure that was determined as appropriate by earlier laboratory studies (Section 230(C)3). If portions of the pads were cut out and placed in solvent in the field, then no further manipulation is necessary before extraction. The date and method of extraction shall be entered on the sample history sheet and the extracts either analyzed immediately or stored under appropriate conditions (Section 230(C)4) for later analysis. If stored, the method of storage must be specified on the sample history sheet.

To reduce laboratory work, pads from opposite sides of the body can be combined prior to extraction. However, if residue values from particular pads are needed for calculations, these pads must be extracted separately. Examples of pads that may not be combined are those from the chest and back and exterior pads adjacent to pads under clothing, which will be used to estimate penetration.

2. Hand rinses

After returning to the laboratory, both right hand rinses are combined into one sample. The same is true for both left hand rinses. Entries are necessary on the sample

Situation 1 - Agricultural Applications, Yards, and Gardens

a. Pesticide identification - chemical name, formulation, EPA registration number, lot number, and type of concentrate container;

b. Investigator's name;

c. Description of area - crop, plot size, and row spacing;

d. Application data - rate, tank capacity type of carrier, final mix concentration, total pounds applied or mixed;

e. Equipment data - type, model;

f. Weather data - relative humidity, wind speed, wind direction, and temperature;

g. Work activity monitored;

h. Location of exposure pads on the subject and sample numbers corresponding to these pads;

i. Exposure observations - direction of travel of applicator in relation to wind direction, and any special situation observed that might alter normal exposure, such as splashing concentrate directly on a particular pad while filling tank; and

j. Exposure time - presented in such a way that total exposure can be calculated per amount of pesticide (or other chemical) handled for the time interval of each work activity.

Situation 2 - Structural Pest Control, Greenhouse, Indoor Residential Applications

a. Pesticide Identification - chemical name, formulation, EPA registration number, lot number, and type of concentrate container;

b. Investigator's name;

c. Description of area - linear feet of baseboard treated, size of room(s);

d. Indoor environmental conditions - ventilation, air exchange rate, if known;

e. Application data - rate, tank capacity, type of carrier, final mix concentration, total pounds applied or mixed;

f. Equipment data - type, model;

g. Weather data - relative humidity and temperature;

h. Work activity monitored;

i. Location of exposure pads on the subject and sample numbers corresponding to these pads;

j. Exposure observations - special situations observed that might alter normal exposure, such as adjusting nozzle or rinsing hands after filling tank; and

k. Exposure time - presented in such a way that total exposure can be calculated per amount of pesticide (or other chemical) handled for the time interval of each work activity.

history sheet for date and method of extraction. If the samples are to be stored, then the method of storage must be noted.

3. Analysis of samples

All samples shall be analyzed by the method(s) meeting the criteria specified in Section 230(C)1. The date and method of analysis shall be noted on the sample history sheet. Fortified substrates should be analyzed along with exposure samples to determine whether total recovery criteria have been met.

F. Presentation of results

1. Standard body surface areas (See also Section V(4)a)

Calculations of total dermal exposure will be performed by the Agency and are therefore not required of the registrant. For the calculation of adult dermal exposures, the following body surface areas will be employed by the Agency: head, 1,300 cm^2 (includes face); back of neck, 110 cm^2; front of neck, 150 cm^2; chest/stomach, 3,550 cm^2; back, 3,550 cm^2; upper arms, 2,910 cm^2; forearms, 1,210 cm^2; hands, 820 cm^2; thighs, 3,820 cm^2; lower legs, 2,380 cm^2; and feet, 1,310 cm^2.

2. Information for dermal exposure calculations

The dermal exposure for any particular body area will be the product of the body surface area given above and the appropriate residue level expressed as ug of residue per cm^2 of exposure pad. Information must be reported so that exposure can be calculated as a function of time engaged in the work activity and as a function of the amount of chemical handled during the work activity. In some cases more than one pad is representative of the area exposed. For these cases the mean of residues found on the appropriate pads will be used. If any pad is found to contain a level of residue that is below the limit of quantification of the procedures employed, the level of residue on the pad will be considered to be half of this limit. The body areas of interest are related to the appropriate exposure pads in Table 2-1.

Final results shall be reported in the text of the report submitted to the Agency as the mean of the exposure per square centimeter of the collection pad for each region of the body. These results must be corrected for total recovery. The number of separate exposures giving rise to each mean and

Table 2-1. Locations of Dermal Exposure Pads that Represent Different Regions of the Adult Body

BODY AREA OF CONCERN	EXPOSURE PADS REPRESENTATIVE OF THE BODY AREA
Totally unprotected head[a]	Shoulder, chest, and back[b]
Face	Chest
Neck	Chest and back
Upper arms	Shoulder and forearm/upper arm
Forearms	Forearm
Hands	Total of residues in the hand rinses,or monitoring gloves is used without regard for surface area.
Chest	Chest
Back	Back
Thighs	Thigh
Calves	Shins
Feet	If necessary, total of residues in socks can be used without regard for surface area.

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[a] Includes face.

[b] Exposure to the head may be estimated by using the mean of the shoulder, back and chest patches or by using a head patch.

See page 2-11 for examples of which pads should not be combined for analysis.

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the range of the exposure shall also be specified. The exposure per square centimeter of the collection pad for each region of the body for each separate exposure must also be submitted to the Agency.

Final results shall also include pertinent field data such as type of application equipment, formulation, tank mix, application rate, pounds of active ingredient handled, crop, and range of weather conditions. All assumptions used in calculations shall also be included. Refer to Section 236 for complete instructions for data reporting requirements.

G. Alternate methodology for the measurement of hand exposures

If the investigator finds that the previously described rinsing procedure is not appropriate in a particular situation for monitoring exposure to the hands, the use of absorbent gloves is acceptable. The use of gloves will require that the studies described in Section C to determine stability and extractability of residues be performed prior to the field study.

Lightweight absorbent gloves provide several advantages over rinsing for the assessment of hand exposure. They can be changed very quickly, trap toxicants that normally would be absorbed during the exposure period, and can be used to collect residues that are insoluble in or are degraded by water or ethanol. The use of gloves may also have certain disadvantages. Gloves may absorb more material than would be retained by the skin, thus overestimating hand exposure. Gloves often contain foreign materials that may interfere with low level analysis. This can be reduced by pre-extraction of gloves with an appropriate solvent.

Two types of lightweight absorbent gloves have proven useful for monitoring hand exposure. One is a white cotton "pallbearer's glove" and the other is a white nylon glove that is often used for fruit packing.

Exposed gloves should be processed in the same manner as exposed dermal pads. In the field, each pair of exposed gloves may either be placed directly into a container of solvent or into a protective envelope inside an unwaxed sandwich bag. Upon returning to the laboratory, both gloves in solvent or both gloves plus their protective envelope are extracted by an appropriate method.

ESTIMATION OF RESPIRATORY EXPOSURE BY PASSIVE DOSIMETRY

Because of the wide differences in chemical and physical properties of the many pesticides that will be investigated, this portion of the guidelines will necessarily be more general than the section on dermal exposure. The specific sampling method, appropriate sampling medium, conditions for storage of samples, and appropriate analytical procedure will largely be dependent on the material being studied. Personal air monitoring will be required and procedures using battery-operated pumps or modified respirators developed by Durham and Wolfe (1962) will be described.

H. Laboratory studies necessary before field studies are initiated

1. Analytical procedure

The choice of analytical procedures will depend on the material being studied and is, therefore, left to the discretion of the investigator. The method must be sufficiently sensitive so that, coupled with the trapping and extraction procedures chosen, it is capable of measuring exposure to 1 ug/hr (or less if the toxicity of the material under study warrents greater sensitivity).

2. Choice of personal monitors

a. Trapping efficiency testing

A trapping efficiency test must be documented for the medium chosen. The procedure described by Melcher et al. (1978), is preferred since it can be performed at approximately the relative humidity expected during field studies. The investigator can adapt this procedure, which was designed for solid sorbents, to all types of sampling media by appropriate modification. Gauze pads can be tested by eliminating the solid sorbent and placing a pad holder between the glass tube containing the "front glass wool plug" and a pump. A filter support assembly such as that available from Ace Glass, Inc. (Catalog No. 7519) may be used to support the pad in the airstream. The gauze pad may have to be trimmed to fit the support, but should be large enough so that all flow is through the pad and no leakage occurs around the periphery. The apparatus used by Melcher will have to be further modified to accommodate the large airflow of this procedure.

If a liquid medium is to be tested, the glass tube containing the "front glass wool plug" is connected directly to the impinger. In all cases, the residue remaining in the "front glass wool plug" and that trapped in the medium must be determined to find the trapping and extraction efficiency:

$$\text{\% efficiency} = \frac{(\text{quantity recovered from medium}) \times 100}{(\text{quantity added to glass wool plug}) - (\text{quantity remaining in glass wool plug})}$$

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Efficiency testing for gauze pads shall be conducted using an airflow near the mean minute ventilation of a man doing light work (29 L/min). If a medium to be used with a personal sampling pump is being tested, then the airflow shall be equal to the maximum that will be used in the field. Tests shall be conducted with the relative humidity of the airflow through the collection medium held at a level based on a reasonable estimate of what the relative humidity might be during the field study. Each test shall be run for a period of time at least as long as the longest exposure time anticipated during field studies. Seven or more separate determinations shall constitute a test.

While it would be desirable to know the trapping efficiency of media using aerosols or particulates, no completely satisfactory procedure is currently available for this type of testing. Registrants are strongly urged to develop an appropriate procedure. Unless aerosols or particulates can be introduced to test the collecting medium when pesticides having very low vapor pressures are used, the investigator will have to determine the retention efficiency of fortified media rather than the trapping efficiency.

To ensure that collected material is not lost from the medium during sampling, the investigator should also test for breakthrough. This can be done by analyzing for any residue that is collected by a trap placed downstream to the medium being tested. This is exemplified by the "back section" of packing in the sampling train described by Melcher et al. (1978). Tests must be performed at high enough residue levels to determine the percentage of breakthrough that will occur if high air concentrations of pesticide are encountered in the field. It is recommended that at least one test be carried out where the initial trap contains ten times the highest amount of residue expected in the field.

b. Criteria of acceptability

The extraction efficiency of laboratory fortified controls will be considered acceptable if the lower limit of the 95 percent interval is greater than 70 percent, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification to calculate the mean and standard deviation for recovery. Total recovery from field fortified samples must be above 50 percent for the study.

3. Exposed media and extract storage

a. Storage of exposed media

If trapping media are to be stored after exposure, a test for the stability of the compound of interest shall be documented. Media shall be charged with a pesticide by the same procedure as was specified above for efficiency testing. Fortified media must be stored under the same conditions that will be used for field samples. The storage stability samples are to be extracted and analyzed by the same methods that will be employed for field samples. Replicate samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage shall be chosen so that the longest corresponds to the longest projected storage period for field samples. A decay curve can then be constructed to determine the appropriate length of storage to meet total recovery criteria.

b. Storage of extracts

If extracts from field samples are to be stored prior to analysis, then a documented study of stability shall be made. Portions of appropriate solvent shall be fortified with levels of authentic concentrate of the same formulation that was used in the field studies and at approximately the same concentration that is expected in extracts from field studies. The fortified samples are to be stored under the conditions to be used for storing extracts from field samples. Each sample should be analyzed immediately before and at appropriate times during storage. The periods of storage shall be chosen so that the longest corresponds to the longest projected storage period for extracts from field samples. A decay curve can then be constructed to determine the length of time to store extracts analysis to meet the total recovery criteria.

I. Personal monitoring using battery-powered pumps

1. Pumps

Several brands of battery-powered personal monitoring pumps are satisfactory for use in estimating an applicator's respiratory exposure to pesticides. However, a pump should be used which is capable of producing an airflow of at least 2 to 4 L/min. and its batteries should be capable of sustaining maximum airflow for at least four hours without recharging.

2. Media containers

Many devices are available for containing the different types of media that may be used for entrapping pesticides during personal air monitoring. These range from elegant spill-proof microimpingers equipped with membrane filters for separate collection of large particulates, to simple tubes used to contain solid sorbents. Most of these devices and their uses were described by Linch (1974). Polyurethane foam plugs have recently become popular for monitoring pesticide exposure and several types of devices to hold these plugs have been described by Lewis et al. (1980) and Davis et al. (1982).

3. Sampling media

A host of different media are also available for trapping pesticides in air. The most suitable media for a particular investigation will depend on the chemical(s) being studied. Ideally, the media should entrap a high percentage of the chemical(s) passing through it, and should allow the elution of a high percentage of the entrapped chemical(s) for analysis. The chemical(s) should be recovered without any conversion to other reaction products, and the media should not produce a significant restriction of airflow. Various media that have proved effective for trapping pesticides have been reviewed by Van Dyk and Visweswariah (1975) and Lewis (1976).

J. Personal monitoring using modified respirators

1. Supplies

a. Respirators

A tight-fitting dust respirator with a removable filter is typically employed. The Willson Dustite (Model CP-2D) produced by Willson Safety Products Division of WGM Safety Corp., Reading, PA, 19603, has been used with good results. Unfortunately, this model is no longer in production. However, if one cannot obtain a similar respirator from another manufacturer, a cartridge type respirator, such as the Willson Paint Spray and Pesticide Respirator (Model CP-122115), may be used.

b. Funnels

Any polyethylene funnel large enough in diameter to cover the dust pad retaining ring of the respirator is satisfactory.

c. Respirator filters

Commercially available dust filters often contain materials that will interfere with chemical analyses, so they should be discarded. Discs the same diameter as the discarded dust filters are cut from a coarse filter paper, such as Whatman No. 4, to serve as backing for the construction of the monitoring pads.

d. Gauze

Any 4 inch (10.2 cm) square gauze surgical sponges that do not contain material that will interfere with analysis are satisfactory. Interfering materials must be preextracted.

e. Storage envelopes to contain exposed pads

Exposed respirator pads may be stored in filter paper envelopes constructed in the same manner as those described in Section 230(A)3.

2. Construction details

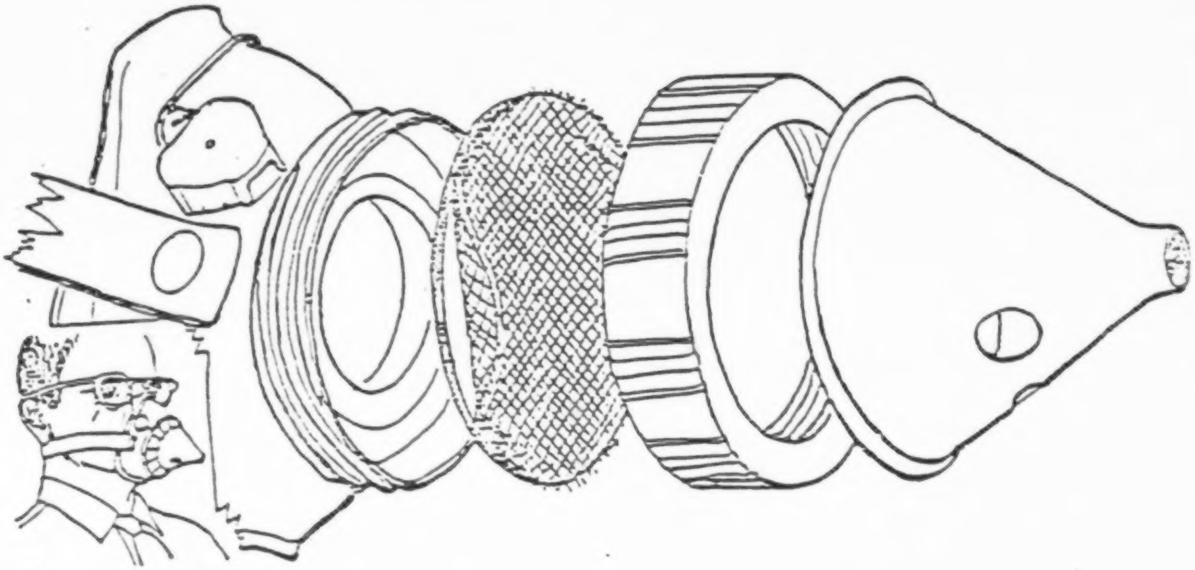
a. Respiratory exposure pads

A disc of filter paper backing is overlaid with 32 plies of gauze, and this combination is stapled around the periphery of the filter. The excess gauze is then trimmed away to conform to the original filter circumference.

b. Respirator modification

The ordinary dust filter is replaced by a gauze fronted filter, which is described above, and the respirator is fitted with an inverted funnel to eliminate direct drift onto the gauze filter. A plastic funnel spout is cut off above the intersection of the spout with the beginning of the conical portion so that a 17 mm hole is produced if using a single-unit respirator, or a 12 mm hole if using a double unit respirator. Durham and Wolfe (1962) plugged the hole and drilled simulated nares in the bottom side of the cone (see Figure 2-1). Their original design presented some problem in attaching the funnel as the holes must point downward. Satisfactory results are obtained using a single hole in the end of the funnel.

Figure 2-1. Single Unit Respirator



The filter pad used for dust is made by stapling 32 layers of surgical gauze to an alpha-cellulose repirator pad (shown partially separated). This pad is held in place by the retaining ring, while the plastic funnel is attached by tape. The complete assembly is shown at the lower left of the illustration.[1]

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[1] Reprinted with permission from the World Health Organization.

K. Field operations

1. Use of personal monitors

The intake tube of any pump powered sampler unit should be positioned so that the opening is downward. This is to avoid collection of large droplets via direct drift, which are not normally drawn into the nostrils. The intake tube should be placed as near as possible to the nose level of the test subject. The height of the intake tube is especially important when taking samples indoors where walls or ceilings are being sprayed. For the study subject's comfort and safety, it is necessary to ensure that the pumps, hoses, and samplers are secured to minimize movement and the potential for snagging.

2. Field calibration of personal monitors

When personal sampler pumps are employed, it is necessary to check the flow at the beginning of the exposure period and again at the end of the exposure period. A convenient flowmeter for this operation is battery operated and will measure flow without disturbance. The Model 541 or 543 portable flow calibrators available from Kurz Instruments, Inc., Carmel Valley, California, 93940, have these characteristics. If flow has been found to change, the mean flow should be used for all calculations.

3. Use of respirators

The use of respirators needs no explanation except that one must make sure that the gauze side of the exposure pad faces out and that the mask is snug. It is advisable to observe the workers periodically as some may remove the mask to wipe off sweat and inadvertently contaminate the exposure pad by wiping the inside of the mask with a contaminated rag. They may also pull the mask down around the neck, if it becomes uncomfortable, thus allowing direct drift onto the inside of the exposure pad. Since respiratory exposure is normally quite low, even slight contamination will lead to large errors.

4. Field fortified samples and blanks

As discussed in Section 230(D)4 for dermal dosimeters, field fortified samples will be needed to ascertain total recovery of residues under conditions of the study(ies). These samples should be fortified at the expected residue levels of actual field samples and prior to the start of the monitoring period. Field fortified samples should be subjected to the same conditions as actual field samples.

There should be at least one per monitoring period. Fortified samples should be stored and analyzed along with field samples collected on the same day.

Field blanks are also necessary to determine if samples become contaminated. There should be at least one field blank per monitoring period. Field blanks should be stored and analyzed with accompanying samples.

5. Handling exposed monitoring media

Respirator pads are removed using clean tweezers and are placed in protective white crepe filter paper envelopes inside sandwich bags. These pads inside envelopes inside sandwich bags are stored in a chest containing ice or an appropriate frozen plastic gel coolant until they are returned to the laboratory, where they should be stored in a freezer prior to extraction.

It is usually most convenient to detach the media container from personal monitors and to store the intact container in a wide-mouth jar inside an ice chest until it is returned to the laboratory. Then, the unit can easily be disassembled to recover the exposed media.

6. Field data collection

Most of the data that must be collected in the field during monitoring for respiratory exposure are the same as those specified for collection during monitoring for dermal exposure (see Section 230(D)5). If personal monitoring pumps are being used, the airflow must also be recorded at the beginning and end of the exposure period. Forms which can be adapted for use in recording these data in the field are shown in Appendix A. Refer to Section 236 for complete data reporting requirements.

L. Laboratory operations subsequent to exposure

As soon as the investigator returns to the laboratory from the field, all samples held in ice chests must be stored in a freezer pending further treatment. A sample history sheet shall be prepared to document laboratory operations. A convenient sheet of this type contains columns labeled: sample number, date sample was collected, date of extraction, date of analysis, and the name(s) of the individual(s) responsible for the task. The lower portion of the sheet contains spaces for recording the conditions of storage for pads, other media, extracts, the extraction procedure employed, and the analytical procedure used. A suggested form of sample history sheet is shown in Appendix B.

1. Extraction of residues from exposed media

Samples are to be extracted according to the procedure that was determined as appropriate by earlier laboratory studies (Section 230(H)2b). The date and method of extraction shall be entered on the sample history sheet and the extracts either analyzed immediately or stored under appropriate conditions (Section 230(H)3) for later analysis. If stored, the method of storage must be specified on the sample history sheet.

2. Analysis of samples

All samples shall be analyzed by the method(s) meeting the criteria specified in Section 230(H)1. The date and method of analysis shall be noted on the sample history sheet.

M. Presentation of results

1. Standard breathing rates

For the sake of standardization so that results collected by various investigators will be comparable, the Agency will use the following values for minute ventilation (Spector, 1956):

Level of Exertion	Ventilation (L/min) Male	Ventilation (L/min) Female
Rest	7.4	4.5
Light work	29	16
Heavy work	60	25

2. Information for inhalation exposure calculations

The final results for respiratory exposure shall be reported in the text of the report submitted to the Agency as the mean residue per liter of air drawn through the sampling media (if sampling pumps are employed). These results shall be corrected for losses due to trapping, extraction, and storage. The number of separate exposures giving rise to the mean and the range of the exposures shall also be specified. If any exposures are below the quantitative limit of the method used for analysis, the number of such exposures shall also be specified. For the purpose of calculating mean residue per liter of air sampled, any samples that contained residues below the limit of quantification should be considered to have contained half this limit. Also, samples should not be considered as valid if the final airflow through the sampling medium was found to be less than 25 percent of the initial airflow. The total time worked during the sampling period and the total quantity of active ingredient handled during the sampling period must be reported. The residue and the total quantity of air drawn through each individual sample shall also be submitted to the Agency.

The final results shall also include pertinent field data such as type of application equipment, formulation, tank mix, application rate, crop, and range of weather conditions. Information pertaining to nozzle type and droplet size produced must also be provided. All assumptions used in calculations shall also be specified. Refer to Section 236 for complete instructions for reporting.

ESTIMATION OF EXPOSURE BY BIOLOGICAL MONITORING

The feasibility of implementing a biological monitoring study is determined by information available on the absorption, distribution, metabolism and excretion profiles of the chemical of interest. A review of all available data in these areas will serve to identify data gaps and to design studies to generate the requisite data. At the current stage of development, biological monitoring should be considered a chemical specific method. Consequently, only general guidance can be provided to assist in the selection of analytical methods, sampling collection schedule and sample storage. Some references which provide guidance in the execution of biological monitoring studies are the work of Franklin et al. (1981, 1983, 1986), Lavy et al. (1980b, 1982) and Kolmodin-Hedman et al.(1983a).

As is the case with passive dosimetry studies, the design of a biological monitoring study should not subject participants to potentially higher exposure than that normally found during routine operations.

N. Studies necessary before field studies are initiated

The pharmacokinetic properties of the chemical being studied should be determined in vivo in an appropriate species.

The studies should include protocols for both dermal and oral administration of the test substance. The dermal studies should be designed to allow an estimation of the rate of absorption of the substrate. Protocols for the above studies should be submitted for evaluation and approval, and they should be identified as components of a biological monitoring study. To the extent possible the protocols should follow procedures in Subdivision F of the Pesticide Assessment Guidelines. The necessary experiments should be conducted to determine the potential for adsorption

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of the test substance or its urinary metabolites to the collection bottles, stability and recovery from the sampling medium and possible breakdown during storage.

O. Field studies

1. Urine sample collection

The recommended procedure involves the collection of 24 hour urine samples. The collection regimen is as follows:

a. At least one, baseline, pre-exposure 24 hour urine sample must be collected; and

b. Samples should be collected for day 1 (application) and post-application days 2,3, etc., as determined by the excretion profile of the pesticide.

A 24 hour urine sample starts with the first void after initiation of the first work activity and is completed with the last void of the 24 hour period. The time and volume of the complete urine void should be reported, along with the age, sex and weight of the study participants.

2. Analytical procedure

The selection of analytical procedures will depend on the particular chemical being studied. Consequently, this decision is left to the discretion of the investigator. The selected procedure should conform to appropriate Agency GLP guidelines (EPA, 1983). The amount of test substance should be reported as a cumulative total for each collection period. The investigator should consider determining creatinine levels as a way of monitoring completeness of urine collection samples.

§231 Requirements for Monitoring Dermal Exposure at Outdoor Sites

A. Outdoor sites

For the purpose of these guidelines, outdoor sites shall include, but not be limited to:

- orchards;
- vegetable and field crop land;
- terrestrial noncrop land;

- aquatic crop and noncrop sites;
- forests;
- home yards and gardens;
- nurseries, turf farms, and golf courses;
- utility lines, roadsides, and rights of way; and
- livestock treatment areas.

B. When studies are required

Field studies of potential dermal exposure during the various work activities involved in the application of pesticide products at outdoor sites under actual use conditions will be required when each of the following criteria is met:

1. the toxicological evaluation of a pesticide product indicates that the use of the product may pose an acute or chronic hazard to human health;
2. dermal exposure is likely to occur during use; and
3. data which would allow the Agency to estimate the magnitude of exposure for a particular work activity with an acceptable degree of confidence are currently unavailable.

C. Number of replicates - dermal exposure

For the purposes of these guidelines, a replicate is defined as measuring dermal exposure to appropriate body parts of an individual over the course of one work cycle or portion thereof. Mixing/loading, application, and equipment clean up shall be considered separate work cycles.

1. Aircraft pilots - A minimum of three (3) replicates each at a minimum of three (3) sites shall be employed. It is recommended that as many different individuals as practicable be monitored.
2. All other workers involved in each work cycle of pesticide application - A minimum of five (5) replicates each at a minimum of three (3) different sites shall be employed. It is recommended that as many different individuals as practicable be monitored.

§232 Requirements for Monitoring Respiratory Exposure at Outdoor Sites

A. When studies are required

Field studies of potential inhalation exposure for the various work activities involved in the application of pesticides at outdoor sites under actual use conditions will be required when each of the following criteria is met:

1. same as 231(B)1 - The toxicological evaluation of a pesticide product indicates that the use of the product may pose an acute or chronic hazard to human health;
2. respiratory exposure is likely to occur during use;
3. same as 231(B)3 - Data which would allow the Agency to estimate the magnitude of exposure for a particular work activity with an acceptable degree of confidence are currently unavailable; and
4. depending on the physicochemical properties of the pesticide product, the conditions of use, and the toxicological effects, it can be expected that exposure by the route of inhalation will be of significant concern as compared to exposure by the dermal route. Field inhalation exposure studies will not be required in all the cases where dermal exposure studies are required.

B. Number of replicates - respiratory exposure

For the purposes of these guidelines, a replicate is defined as measuring potential inhalation exposure using a personal monitoring device for an individual over the course of one work cycle or portion thereof.

1. Aircraft pilots (same as 231(C)1) - A minimum of three (3) replicates each at a minimum of three (3) sites shall be employed. It is recommended that as many different individuals as practicable be monitored.
2. Other workers (same as 231(C)2) - A minimum of five (5) replicates each at a minimum of three (3) sites shall be employed. It is recommended that as many different individuals as practicable be monitored.

C. Combined testing

When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.

§233 Requirements for Monitoring Dermal Exposure at Indoor Sites

A. Indoor sites

For the purpose of these guidelines, indoor sites shall include, but not be limited to:

- homes and apartments;
- greenhouses;
- barns and other farm buildings;
- commercial buildings and manufacturing facilities;
- restaurants and food handling and processing facilities;
- fumigation facilities, warehouses, railroad boxcars;
- schools, hospitals and other health care facilities; and
- mushroom houses.

B. When studies are required

Field studies of potential dermal exposure during the various work activities involved in the application of pesticides at indoor sites under actual use conditions will be required when each of the following criteria is met:

1. same as in 231(B)1 - The toxicological evaluation of a pesticide product indicates that the use of the product may pose an acute or chronic hazard to human health;
2. same as in 231(B)2 - Dermal exposure is likely to occur during use; and
3. same as in 231(B)3 - Data which would allow the Agency to estimate the magnitude of exposure for a particular work activity with an acceptable degree of confidence are currently unavailable.

C. Methodology

During application the same techniques for measuring potential dermal exposure employed in Section 231 shall be used. Post-application measurements of exposure also employ the same techniques described in Section 231, but will be required only on a case by case basis depending on the type of pesticide product and its use.

D. Number of replicates - dermal exposure

For exposure during application, a minimum of five (5) replicates each at a minimum of three (3) representative indoor sites shall be employed. It is recommended that as many individuals as practicable be monitored.

§234 Requirements for Monitoring Respiratory Exposure at Indoor Sites

A. When studies are required

Field studies of potential inhalation exposure during the various work activities involved in the application of pesticides at indoor sites under actual use conditions and of potential inhalation exposure to individuals post-application will be required when each of the following criteria is met:

1. same as 231(B)1 - The toxicological evaluation of a pesticide product indicates that the use of the product may pose an acute or chronic hazard to human health;

2. same as 232(A)2 - Respiratory exposure is likely to occur during use and/or for a period of time after use;

3. same as 231(B)3 - Data which would allow the Agency to estimate the magnitude of exposure for a particular work activity and post work activity with an acceptable degree of confidence are currently unavailable; and

4. **same** as 232(A)4 - Depending on the physicochemical properties of the pesticide product, the conditions of use, and the toxicological effects, it can be expected that exposure by the route of inhalation will be of significant concern as compared to exposure by the dermal route. Field inhalation exposure studies will not be required in all the cases where dermal exposure studies are required.

B. Methodology

1. During application - The same techniques for measuring potential respiratory exposure employed in Section 232 shall be used.

2. Post-application - The same techniques employed in Section 232 shall be used, except that the monitor may be fixed at a location in the room at a height representative of the breathing zone of the individual. Potential respiratory exposure should be monitored for appropriate periods of time on a schedule of days such that the pattern of decline of potential respiratory exposure as a function of time can be defined for the persons typically present at the indoor site.

C. Number of replicates - respiratory exposure

For exposure during application, a minimum of five (5) replicates each at a minimum of three (3) representative indoor sites shall be employed. Post-application exposure shall be monitored at each site. One replicate per time point is required. It is recommended that as many individuals as practicable be monitored.

D. Combined testing

When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.

§235 Requirements for Monitoring Exposure at Outdoor and Indoor Sites by Biological Monitoring

A. When studies are required

Biological monitoring studies may be employed to estimate exposure as an alternative to passive dosimetry at outdoor and indoor sites when each of criteria (1) through (4) is satisfied, and will be required when all five of the following criteria are met:

1. same as 231(B)1 - The toxicological evaluation of a pesticide product indicates that the use of the product may pose an acute or chronic hazard to human health;

2. exposure is likely to occur during use;

3. same as 231(B)3 - Data which would allow the Agency to estimate the magnitude of exposure for a particular work activity with an acceptable degree of confidence are currently unavailable;

4. the pharmacokinetics of a pesticide (or other component in a pesticide product) is sufficiently understood so that a back calculation to actual dose is possible; and

5. passive dosimetry techniques are determined not to be applicable for a particular exposure scenario.

B. Number of replicates

For the purposes of biological monitoring in these guidelines, a replicate is defined as measuring total exposure to an individual which occurs over the course of a work day or portion thereof.

1. Aircraft pilots and other workers where available study participants may be limited - A minimum of three (3) replicates each at a minimum of three (3) sites shall be employed. It is recommended that as many different individuals as practicable be monitored.

2. All other workers involved in each work cycle of pesticide application - A minimum of five (5) replicates each at a minimum of three (3) sites shall be employed. It is recommended that as many different individuals as practicable be monitored.

§236 Applicator Exposure Monitoring Data Reporting

The following is a suggested report format. If, in the registrant's opinion, a better format would result in a more efficient review by the Agency, it may be used. However, the information described herein must be included.

A. Title page

The title page should conform with existing Agency requirements or as described in Requirements for Data Submission (EPA, 1984; see Appendix C).

B. Table of contents

The table of contents should indicate the overall organization of the report and list the page numbers for the different sections. Tables, figures, and appendices should be listed separately. (Section tabs would be of help to the Agency in its review.)

C. Introduction and summary

This section should open with a description of the purpose of the study and what requirement(s) it is intended to satisfy. Background and historical information relative to the study should be placed in this section.

The introduction and summary section should also contain an overall summary of the study and mention, at a minimum, the following points:

1. the chemical (use the name used throughout the report and indicate the formulation) was applied according to actual practice to the primary crop;
2. the application rate in units of active ingredient/unit of area, volume of spray/unit of area, and total units of active ingredient handled during each work activity;
3. the number of individuals involved in the study, indicating duties and clothing worn during each work activity monitored;
4. indicate unusual problems (such as spills, unusual weather, or equipment failure) resulting in necessary deviation from the intended test protocol. Describe the effects of these deviations in the results of the study; and
5. provide a name and a phone number of a contact person in the event the reviewer has technical questions about the study.

D. Materials and methods

This section should be in narrative form, and should contain (in the following order) all details with regards to the materials, equipment, experimental design, site description, and procedures used in conducting the study. The registrant is encouraged to include drawings or preferably photographs of the test site equipment, and the workers that show the placement of monitoring devices.

In this section, the following should be included:

1. chemical - The name of the active ingredient, CAS number, formulation and percent or concentration of active ingredient and impurities; EPA registration number; lot number; type of container, and chemical trade name;

2. site - A description of the test site indicating the location, crop, row spacing, and acres treated for outdoor applications and location, room size, size of surface treated, ventilation during and after application, and the air exchange for indoor applications; and

3. test method - For all applications a description of the application rate, spray tank capacity, type of carrier and other additives, final mix concentration, total lbs. active ingredient applied or mixed, and the mixing procedures.

   a. For outdoor applications a detailed description of the application and mixing/loading equipment including nozzle type, height from the ground and the top of the crop, nozzle pressure, ground speed, boom length, and cab description shall also be provided when applicable.

   b. For indoor applications a detailed description of the application equipment including type of spray nozzle shall be provided.

   c. A description of the subjects used in the study. This shall include work function, clothing worn (including protective clothing), placement of all monitoring devices on the subjects, and the duration of the monitored work function.

   d. A detailed description of the monitoring devices. This description shall specify the material and brand of the devices used for passive dosimetry including total area and the area of the surface exposed to the test chemical. The description of any air sampling devices shall include brand, air flow rate, and the type of trapping device used including the composition of the material in the collection media.

   e. A description of the laboratory studies conducted prior to initiating the field studies. This shall include a description of the methodology used to determine test chemical stability on the collection media, the efficiency of extraction, and stability of the extracts.

   f. A description of the handling of samples from the time they were taken in the field through analysis with special attention to the conditions under which the samples were stored. In addition, the handling of storage stability samples to be used in determining if the pesticide residues are stable under storage conditions shall be described.

g. A description of the required field stability, field fortification, and field blank tests will be included. This will provide a description of the exposure media, method of fortification, environmental conditions to which the fortified media was exposed, and a description of the handling of the samples from field collection to laboratory analysis.

h. Elaboration on the difficulties or special problems that arose during the study that necessitated deviation from the intended test protocol and on the effects the deviations had on the results. This is intended to include such circumstances as equipment failure and repair which may affect the exposure monitoring.

E. Analytical method

The methods used in the study for each test (i.e. efficiency of extraction, field fortification) are to be described fully and include method validation data, recovery and method sensitivity data, stability data, sample chromatograms, and sample calculations. Preparation and handling of the samples throughout the method should be described in detail.

Identify the instrumentation, equipment, reagents used and the operating conditions of the instruments. If the extraction/clean-up procedure is complex, then a flow diagram of it should be submitted. Extraction efficiencies, recoveries, precision and limit of detection need to be reported along with the technique used to determine these parameters for each method.

F. Results

This section should contain the scientific results of the study and must be interpretive. Narrative and tables describing all calculations should be presented. The results shall be reported as described in Section 230 [(F)3 and (M)2] of the guidelines. A sample calculation for each separate mathematical manipulation must be provided.

G. Discussion and conclusions

Because the ultimate determination of the exposure produced by the use of a pesticide rests with the Agency, these sections are optional.

H. Quality assurance

Name (including signature and date) of the person(s) responsible for the major quality control (QC) duties, should be included. Also included should be the procedures undertaken by the registrant/laboratory to validate the report. This may be a list of all audits and reviews performed that includes the study activity, the date activities were performed, and the individual(s) involved. Any deficiencies and subsequent corrective action taken should be described.

I. Location of raw data and final report

The name and address of the facility in which the raw data and final report are reposed must be reported.

J. Signature page

This page shall contain the dated signatures of all professionals and scientists involved with or responsible for the study.

K. Tables and figures

Tables and figures are to be numbered using Arabic numerals rather than Roman numerals or letters.

L. References

References must be in a standard and consistent format.

M. Appendices

The appendices should contain:

1. copy of all relevant communications;
2. a copy of the Agency approved study protocol and all subsequent amendments to the protocol;
3. a copy of all appropriately filled out and completed exposure data reporting survey forms as shown in Appendix A. This is important since it is necessary for the Agency to calculate exposure directly from the raw data and also to facilitate entry into the computerized data base; and
4. sample chromatograms, diagrams, photographs or other pictorial material.

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List of Appendices

Appendix

A Exposure Data Reporting Survey Forms

B Exposure Sample History Sheet

C Federal Register Notice 49/188-
Format of Data Submitted to the Agency

Appendix A

Exposure Data Reporting Survey Forms

INSTRUCTIONS FOR FILLING OUT SURVEY FORMS

These instructions pertain to the following four sets of survey forms developed to code exposure monitoring data for the creation of a generic data base. The survey forms are categorized by work activity and include exposure to mixers/loaders, applicators, flaggers, and a combined mixer/loader/applicator form. Most of the information requested is self-explanatory and further clarification is given when necessary. In the instances when you are given a few numbered choices, circle the appropriate response. Please do not leave any blanks on the forms. If any category is not applicable to your study, please indicate this by writing "N/A".

A single set of survey forms is to be completed for each replicate in a study. A REPLICATE CONSISTS OF ALL SAMPLE VALUES TAKEN FOR ONE WORKER DURING ONE WORK CYCLE (WORK PERIOD, SAMPLE PERIOD, MONITORING PERIOD, EXPERIMENTAL RUN, ETC.) Therefore, one set of forms will be used for each worker and work cycle monitored. Foreseeably, a substanial amount of information mentioned will be the same for each work cycle within a given study. Information which may be redundant is marked with an asterisk and need not be repeated. Discretion is needed to determine whether the information marked with an asterisk is truly the same. If the information is different, fill in the new information.

Along with the four sets of survey forms, there is one set of Quality Assurance forms to be completed for each study. If a single study was carried out at more than one site, then the QA forms should be completed for each site.

Study Code No. - This item located in the upper left hand corner is for EPA/contractor use only. Each study/report that is submitted will be given a numerical designation, which will also be written on the corresponding survey forms in this box.

Worker I.D./Work Cycle No. - These two items located in the upper right hand corner of the survey forms are necessary in order to ensure a unique identification in the data base for each worker and work cycle. Before completing the survey forms, assign a unique one or two letter code to each worker monitored in the study. Then assign a one or two digit number to each work cycle in the study. When completing the survey forms, indicate the unique letter code for the worker and the corresponding number code for the work cycle in the appropriate spaces in the upper right hand corner. For example, B-3 represents Worker B in the third work cycle of the study. If the information marked with an asterisk applies to more than one set of forms, please identify the Worker I.D. and Work Cycle Number of the completed form which contains this information. In the example to the left, information that will not be recorded on the survey forms labeled B-3, can be taken from the forms labeled A-1. If all the information requested on the forms will be completed, please write "N/A" in the lower half of the box labeled "Location of * Data".

EXAMPLE

Worker I.D.	Work Cycle Number
B	3

Location of * Data:

Worker I.D.	Work Cycle Number
A	1

Compound Identification:

Formulation

For certain compounds, the amount of actual active ingredient must be reported. For example, several forms of 2,4-D are registered as active ingredients. In this case, the weight of 2,4-D acid equivalents shall be reported.

#5 Liquid: fumigant or ready to use home product.

Site Data:

Crop Height - specify the height of the crop in feet; insert "zero" in cases where the pesticide is applied to bare soil.

Application Information:

Describe Application Procedure - in detail; be sure to include any aspects of the application which are not captured on the forms, but which may be relevant to interpretation of the data, e.g. simultaneous incorporation.

Airborne Exposure Data:

Amount of Chemical Collected (ug) - including particulates and vapors.

Air Volume Collected (L) - is obtained from the formula $\frac{(R_i + R_f)t}{2}$ where R_i and R_f are the initial and final pumping rates in L/min. and t is the sampling duration in minutes.

Dermal Exposure Values - list the exposure values in ug/cm^2 of collection medium for the anatomical areas in which data were collected. Do not extrapolate values from one location to estimate exposure for another location on which data were not collected. If you only have combined data from the left and right sides of the body, put this combined value in the right column and write "C" (for combined) in the left column. If, for whatever reason, you do not have sample values for any of the anatomical regions listed, write "N/A" in the column(s).

If a study includes more than one set of inside patches (e.g. under protective clothing as well as under personal clothing), the results of only one set shall be reported for any body part. Under the column labeled 'location' enter 1 if the inside patch is under personal clothing, enter 2 if it is under protective clothing, or enter 3 if it is under both. Do this for each inside patch.

If residues are measured on an entire body part, excluding hands, (e.g. when using the WHO protocol), then the data must be reduced to ug/cm^2 using the surface areas listed in the table.

Mixing/Loading Information:

Describe Mixing Procedures and Equipment - in detail; be sure to include any aspects of the mixing or loading which are not captured on the forms, but which may be relevant to interpretation of the data.

Study Code No:________
(EPA Use Only)

Worker I.D. ______ | Work Cycle Number ______
Do Not Leave Blank

APPLICATOR EXPOSURE SURVEY FORM

(ONE FORM PER REPLICATE)

Location of * Data:
Worker I.D. ______ | Work Cycle Number ______
See Instructions

Sampling Date________________________________

Time of Day Monitoring Took Place (use military time):

From__________ To__________

COMPOUND IDENTIFICATION *Action of Pesticide: 1) Fungicide 2)Herbicide 3) Insecticide 4) Fumigant 5) Plant Growth Regulator

*Formulation: Liquid (lb ai/gal)__________ OR Solid (% ai by weight)__________

Liquid	Solid
1) Emulsifiable Concentrate	1) Wettable-powder
2) Suspension (aqueous)	2) Dry-flowable
3) Microencapsulated	3) Dust
4) Solution	4) Granule
5) Liquid (undiluted; e.g. fumigant)	

SITE DATA *Location (state/province and country)____________________________

*(check one)______Indoor or ______Outdoor *Crop____________________________

*Crop Height (feet)____________________ *Row Spacing (feet)____________________

APPLICATION INFORMATION *Method of Application:

1) Airblast
2) Groundboom Tractor
3) Groundboom Truck
4) Groundboom Rail Car
5) Aerial - Fixed Wing
6) Aerial - Rotary Wing
7) Low Pressure Hand Wand
8) High Pressure Hand Wand (attached to truck)
9) Backpack
10) Shank Injection
11) Fumigation
12) Solid Broadcast Spreader
13) Liquid Broadcast Spreader
14) Other (describe)

If 14, describe____

____

____

Rate: (lb ai/acre)________and (gal/acre)________ Total lb ai Applied__________

Total # Acres Treated________ Final Mix Concentration (lb ai/gal Diluent)________

Total # Gallons Sprayed______________ # Tank Applications Monitored______________

*Vehicle Make and Model:____

____

*Cab Type:
1) Open Cab(Cockpit)
2) Closed Cab(Cockpit)/Window Open
3) Closed Cab(Cockpit)/Window Closed
4) Closed Cab(Cockpit)/Window Closed/Filtered Air

Study Code No:________

(EPA Use Only)

APPLICATOR EXPOSURE SURVEY FORM - 2

Worker I.D.	Work Cycle Number
_____	______

Do Not Leave Blank

APPLICATION INFORMATION CONTINUED Ground Speed (mph)____________

Location of * Data:

Worker I.D.	Work Cycle Number
_____	______

See Instructions

*Applicator Make and Model:_______________________________________

*Disc # ___________________ *# Nozzles__________

*Nozzle: Type/Manufacturer___________________ Model/No.__________

*Nozzle Pressure (psi)__________ *Boom Height Above Ground (feet)______

*Swath Width (feet)__________ *Length of Boom (feet)__________

*Shank/Probe Type: 1) Knives 2) Sweeps 3) Other

*Depth of Injection/Incorporation (inches)__________

Describe Application Procedure_______________________________________

WEATHER DATA % Relative Humidity: High__________ and Low__________

Temperature (Fahrenheit): High__________ and Low__________

Wind Speed: 1) 0-5 mph 2) 6-10 mph 3) >10 mph

Wind Direction Relative to Travel: 1) Parallel 2) Perpendicular 3) Other

If 3, explain_______________________________________

PERSONAL INFORMATION Is Study Participant a: 1) Private Applicator
2) Commercial Applicator 4) Non-Certified Applicator
3) Certified Applicator 5) Other

Years of Experience as an Applicator: 1) <1 2) 1-5 3) 6-10 4) 11-15
5) 16-20 6) >20

PERSONAL CLOTHING Pants: 0) None 1) Long-legged 2) Short-legged

Shirt: 0) None 1) Long-sleeved 2) Short-sleeved Jacket: 0) No 1) Yes

Shoes/Boots: 0) None 1) Rubber 2) Fabric 3) Leather

PERSONAL PROTECTIVE EQUIPMENT Hat: 0) No 1) Yes

Protective Suit/Coveralls: 0) None 1) Rubber 2) Fabric 3) Disposable

Eye/Face Protection: 0) None 1) Goggles 2) Face Shield 3) Safety Glasses

Gloves: 0) None
1) Wrist Length Rubber/Plastic
2) Wrist Length Fabric
3) Wrist Length Leather
4) Mid-Forearm Rubber/Plastic
5) Elbow Length Rubber/Plastic

Study Code No: ________

(EPA Use Only)

APPLICATOR EXPOSURE SURVEY FORM - 3

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

AIRBORNE EXPOSURE DATA *Technique Used: 1) Filter on Respirator 2) Personal Air Pump 3) Fixed Location

If 3, specify location ____

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

Air Sampling Time (min) __________ Quantification Limit (ug) __________

Amount of Chemical Collected (ug) __________ Air Volume Collected (L) __________

Flow Rate (L/min): Initial ____________ Final ____________ Average ____________

DERMAL EXPOSURE DATA Dermal Sampling Time (hrs) ____________________

*Method of Measuring Dermal Exposure Excluding Hands:

1) Patch Technique 2) Solvent Rinse 3) Clothing 4) Other

If 1, describe patch construction (i.e. gauze, alpha-cellulose, etc.) ______

____

____

If 2, type of solvent ____

____

If 3, describe clothing ____

____

If 4, describe ____

____

*Method of Measuring Hand Exposure: 1) Hand Rinse 2) Gloves 3) Other

If 1, type of solvent ____

____

If 2, describe gloves ____

____

____

If 3, describe ____

____

Study Code No:_______

(EPA Use Only)

APPLICATOR EXPOSURE SURVEY FORM - 4

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

Dermal Exposure Values Excluding Hands (ug/cm2):

Inside Clothing			location (enter 1,2 or 3)	Outside Clothing	
Head	______		____	______	
Neck Front	______		____	______	
Neck Back	______		____	______	
Upper Arms	(R)______	(L)______	____	(R)______	(L)______
Shoulders	(R)______	(L)______	____	(R)______	(L)______
Chest	(R)______	(L)______	____	(R)______	(L)______
Back	(R)______	(L)______	____	(R)______	(L)______
Forearms	(R)______	(L)______	____	(R)______	(L)______
Hips	(R)______	(L)______	____	(R)______	(L)______
Thighs	(R)______	(L)______	____	(R)______	(L)______
Shins	(R)______	(L)______	____	(R)______	(L)______
Calves	(R)______	(L)______	____	(R)______	(L)______
Ankles	(R)______	(L)______	____	(R)______	(L)______
Feet	(R)______	(L)______	____	(R)______	(L)______

Average Quantification Limit (ug/cm2)____________________

Hand Exposure Values (ug):

(R)____________________ (L)____________________ Both____________________

Average Quantification Limit (ug):____________________

If incidental contact with the pesticide was observed, please circle the response(s) that best describe(s) the situation:

1) Observed Hand Contact
2) Observed Face Contact
3) Observed Contact with Other Body Parts

Please Provide a Brief Description of the Incidental Exposure Situation________

____

____

____

Study Code No:________

(EPA Use Only)

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

MIXER/LOADER EXPOSURE SURVEY FORM

(ONE FORM PER REPLICATE)

Location of * Data:

Worker I.D.	Work Cycle Number
______	______

See Instructions

Sampling Date______________________________

Time of Day Monitoring Took Place (use military time):

From__________To__________

COMPOUND IDENTIFICATION *Action of Pesticide: 1) Fungicide 2) Herbicide 3) Insecticide 4) Fumigant 5) Plant Growth Regulator

*Formulation: Liquid (lb ai/gal)__________ OR Solid (% ai by weight)__________

1) Emulsifiable Concentrate	1) Wettable-powder
2) Suspension (aqueous)	2) Dry-flowable
3) Microencapsulated	3) Dust
4) Solution	4) Granule
5) Liquid (undiluted; e.g. fumigant)	

*Packaging Type: 1) Bag 2) Can 3) Bottle 4) Water Soluble Packet

*Container Size______________________________

SITE DATA *Location (state/province and country)______________________________

*(check one)______Indoor or ______Outdoor

MIXING/LOADING INFORMATION

*Mixing Procedures: 1) Open 2) Closed, Mechanical Pump 3) Closed, Gravity Feed

If closed system is used, specify make and model______________________________

____

*Type of Diluent: 1) Water 2) Oil, Vegetable 3) Oil, Petroleum 4) Solvent

Final Mix Concentration (lb ai/gal Diluent)________Total # Gallons Mixed________

Tank Mixes Monitored__________________ Total Amount of ai Mixed (lb)__________

*Tank/Hoppers Capacity (gal/lbs) ______________________________

Other Tank Additives:

- 0) None
- 1) Spreader/Sticker
- 2) Surfactant
- 3) Dye
- 4) Other Pesticide

Describe Mixing Procedures and Equipment______________________________

____

____

Study Code No:_______

(EPA Use Only)

MIXER/LOADER EXPOSURE SURVEY FORM - 2

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

WEATHER DATA

% Relative Humidity: High_______________ and Low_______________

Temperature (Fahrenheit): High___________ and Low_______________

Wind Speed: 1) 0-5 mph 2) 6-10 mph 3) >10 mph

Wind Direction Relative to Mixing: 1)Face to Wind 2)Back to Wind 3)Crosswind 4)Other

If 4, explain____

PERSONAL CLOTHING

Pants: 0) None 1) Long-legged 2) Short-legged

Shirt: 0) None 1) Long-sleeved 2) Short-sleeved

Jacket: 0) No 1) Yes

Shoes/Boots: 0) None 1) Rubber 2) Fabric 3) Leather

PERSONAL PROTECTIVE EQUIPMENT

Protective Suit/Coveralls: 0) None 1) Rubber 2) Fabric 3) Disposable

Hat: 0) No 1) Yes

Eye/Face Protection: 0) None 1) Goggles 2) Face Shield 3) Safety Glasses

Gloves:
- 0) None
- 1) Wrist Length Rubber/Plastic
- 2) Wrist Length Fabric
- 3) Wrist Length Leather
- 4) Mid-Forearm Rubber/Plastic
- 5) Elbow Length Rubber/Plastic

AIRBORNE EXPOSURE DATA

*Technique Used: 1) Filter on Respirator 2) Personal Air Pump 3) Fixed Location

If 3, specify location____

Air Sampling Time (min)__________________ Quantification Limit (ug)___________

Amount of Chemical Collected (ug)__________ Air Volume Collected (L)___________

Flow Rate (L/min): Initial_____________Final_____________Average_____________

Study Code No:_______

(EPA Use Only)

MIXER/LOADER EXPOSURE SURVEY FORM - 3

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

DERMAL EXPOSURE DATA

Dermal Sampling Time (hrs)____________________

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

*Method of Measuring Dermal Exposure Excluding Hands:

1) Patch Technique 2) Solvent Rinse 3) Clothing 4) Other

If 1, describe patch construction (i.e. gauze, alpha-cellulose, etc.)______

If 2, type of solvent____________________

If 3, describe clothing____________________

If 4, describe____________________

*Method of Measuring Hand Exposure: 1) Hand Rinse 2) Gloves 3) Other

If 1, type of solvent____________________

If 2, describe gloves____________________

If 3, describe____________________

Study Code No:_______

(EPA Use Only)

MIXER/LOADER EXPOSURE SURVEY FORM - 4

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

Dermal Exposure Values Excluding Hands (ug/cm2):

Inside Clothing			location (enter 1,2 or 3)	Outside Clothing	
Head	________		____	________	
Neck Front	________		____	________	
Neck Back	________		____	________	
Upper Arms	(R)________	(L)________	____	(R)________	(L)________
Shoulders	(R)________	(L)________	____	(R)________	(L)________
Chest	(R)________	(L)________	____	(R)________	(L)________
Back	(R)________	(L)________	____	(R)________	(L)________
Forearms	(R)________	(L)________	____	(R)________	(L)________
Hips	(R)________	(L)________	____	(R)________	(L)________
Thighs	(R)________	(L)________	____	(R)________	(L)________
Shins	(R)________	(L)________	____	(R)________	(L)________
Calves	(R)________	(L)________	____	(R)________	(L)________
Ankles	(R)________	(L)________	____	(R)________	(L)________
Feet	(R)________	(L)________	____	(R)________	(L)________

Average Quantification Limit (ug/cm2)________________

Hand Exposure Values (ug):

(R)________________ (L)________________ Both________________

Average Quantification Limit (ug):________________

If incidental contact with the pesticide was observed, please circle the response(s) that best describe(s) the situation:

1) Observed Hand Contact
2) Observed Face Contact
3) Observed Contact with Other Body Parts

Please Provide a Brief Description of the Incidental Exposure Situation________

____

____

____

Study Code No:_______

(EPA Use Only)

FLAGGER EXPOSURE SURVEY FORM

(ONE FORM PER REPLICATE)

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

Sampling Date___________________________

Time of Day Monitoring Took Place (use military time):

From________ To_________

COMPOUND IDENTIFICATION *Action of Pesticide: 1) Fungicide 2) Herbicide 3) Insecticide 4) Fumigant 5) Plant Growth Regulator

*Formulation: Liquid (lb ai/gal)_________ OR Solid (% ai by weight)_________

Liquid	Solid
1) Emulsifiable Concentrate	1) Wettable-powder
2) Suspension (aqueous)	2) Dry-flowable
3) Microencapsulated	3) Dust
4) Solution	4) Granule
5) Liquid (undiluted; e.g. fumigant)	

SITE DATA *Location (state/province and country)__________________________

*Crop____________________________ *Crop Height (feet)_________________

*Row Spacing (feet)__________________

APPLICATION INFORMATION

*Method of Application:

1) Aerial - Rotary Wing 2) Aerial - Fixed Wing

*Airplane or Helicopter Make and Model____________________________________

____

Rate: (lb ai/acre)_______ and (gal/acre)________ Total lb ai Flagged________

Total # Acres Treated________ Final Mix Concentration (lb ai/gal Diluent)______

Total # Gallons Sprayed____________ # Tank Applications Monitored____________

Ground Speed of Plane (mph)__________________

*Describe Spray Equipment:____

____

____

*Disc # __________________________ *# Nozzles________________________

Study Code No:________

(EPA Use Only)

FLAGGER EXPOSURE SURVEY FORM - 2

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycl Number
_____	_____

See Instructions

APPLICATION INFORMATION CONTINUED

*Nozzle Pressure (psi)________________________________

*Boom Height Above Ground (feet)________________________

*Nozzle: Type/Manufacturer______________________Model/No.____________

*Swath Width (feet)______________ *Length of Boom (feet)____________

Describe Flagging Procedure______________________________________

____

Was Flagger Positioned:

(check one)______In Treatment Area or ______On Perimeter of Treatment Area

WEATHER DATA

% Relative Humidity: High____ ______________ and Low__________________

Temperature (Fahrenheit): High______________ and Low__________________

Wind Speed: 1) 0-5 mph 2) 6-10 mph 3) >10 mph

Flagger Position Relative to Treatment Area:

1) Upwind 2) Downwind 3) Crosswind

PERSONAL CLOTHING

Pants: 0) None 1) Long-legged 2) Short-legged

Shirt: 0) None 1) Long-sleeved 2) Short-sleeved

Jacket: 0) No 1) Yes Shoes/Boots: 0) None 1) Rubber 2) Fabric 3) Leather

PERSONAL PROTECTIVE EQUIPMENT

Protective Suit/Coveralls: 0) None 1) Rubber 2) Fabric 3) Disposable

Hat: 0) No 1) Yes

Eye/Face Protection: 0) None 1) Goggles 2) Face Shield 3) Safety Glasses

Gloves:
0) None
1) Wrist Length Rubber/Plastic
2) Wrist Length Fabric
3) Wrist Length Leather
4) Mid-Forearm Rubber/Plastic
5) Elbow Length Rubber/Plastic

Study Code No: ________

(EPA Use Only)

FLAGGER EXPOSURE SURVEY FORM - 3

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
______	______

See Instructions

AIRBORNE EXPOSURE DATA *Technique Used: 1) Filter on Respirator 2) Personal Air Pump 3) Fixed Location

If 3, specify location ______________________________

____

Air Sampling Time (min) ____________ Quantification Limit (ug) ____________

Amount of Chemical Collected (ug) ____________ Air Volume Collected (L) ____________

Flow Rate (L/min): Initial ____________ Final ____________ Average ____________

DERMAL EXPOSURE DATA Dermal Sampling Time (hrs) ____________

*Method of Measuring Dermal Exposure Excluding Hands:

1) Patch Technique 2) Solvent Rinse 3) Clothing 4) Other

If 1, describe patch construction (i.e. gauze, alpha-cellulose, etc.) ________

____

____

If 2, type of solvent ______________________________

____

If 3, describe clothing ______________________________

____

If 4, describe ______________________________

____

*Method of Measuring Hand Exposure: 1) Hand Rinse 2) Gloves 3) Other

If 1, type of solvent ______________________________

____

If 2, describe gloves ______________________________

____

____

If 3, describe ______________________________

____

Study Code No: ________

(EPA Use Only)

FLAGGER EXPOSURE SURVEY FORM - 4

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

Dermal Exposure Values Excluding Hands (ug/cm2):

	Inside Clothing		location (enter 1,2 or 3)	Outside Clothing	
Head	________		____	________	
Neck Front	________		____	________	
Neck Back	________		____	________	
Upper Arms	(R) ________	(L) ________	____	(R) ________	(L) ________
Shoulders	(R) ________	(L) ________	____	(R) ________	(L) ________
Chest	(R) ________	(L) ________	____	(R) ________	(L) ________
Back	(R) ________	(L) ________	____	(R) ________	(L) ________
Forearms	(R) ________	(L) ________	____	(R) ________	(L) ________
Hips	(R) ________	(L) ________	____	(R) ________	(L) ________
Thighs	(R) ________	(L) ________	____	(R) ________	(L) ________
Shins	(R) ________	(L) ________	____	(R) ________	(L) ________
Calves	(R) ________	(L) ________	____	(R) ________	(L) ________
Ankles	(R) ________	(L) ________	____	(R) ________	(L) ________
Feet	(R) ________	(L) ________	____	(R) ________	(L) ________

Location of * Data:

Worker I.D.	Work Cycle Number
______	______

See Instructions

Average Quantification Limit (ug/cm2)____________________

Hand Exposure Values (ug):

(R)________________ (L)________________ Both________________

Average Quantification Limit (ug):____________________

If incidental contact with the pesticide was observed, please circle the response(s) that best describe(s) the situation:

1) Observed Hand Contact
2) Observed Face Contact
3) Observed Contact with Other Body Parts

Please Provide a Brief Description of the Incidental Exposure Situation__________

____

____

____

Study Code No: ________

(EPA Use Only)

MIXER/LOADER/APPLICATOR EXPOSURE SURVEY FORM

(ONE FORM PER REPLICATE)

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
______	______

See Instructions

Sampling Date ______________________________

Time of Day Monitoring Took Place (use military time):

From ________ To ________

|COMPOUND IDENTIFICATION| *Action of Pesticide: 1) Fungicide 2)Herbicide 3) Insecticide 4) Fumigant 5) Plant Growth Regulator

*Formulation: Liquid (lb ai/gal)________ OR Solid (% ai by weight)________

1) Emulsifiable Concentrate	1) Wettable-powder
2) Suspension (aqueous)	2) Dry-flowable
3) Microencapsulated	3) Dust
4) Solution	4) Granule
5) Liquid (undiluted; e.g. fumigant)	

*Packaging Type: 1) Bag 2) Can 3) Bottle 4) Water Soluble Packet

*Container Size ______________________________

|SITE DATA| *Location (state/province and country)______________________________

*(check one)_____Indoor or _____Outdoor *Crop ______________________________

*Crop Height (feet)____________________ *Row Spacing (feet)__________________

|MIXING/LOADING INFORMATION|

*Mixing Procedures: 1) Open 2) Closed, Mechanical Pump 3) Closed, Gravity Feed

If closed system is used, specify make and model______________________________

____

*Type of Diluent: 1) Water 2) Oil, Vegetable 3) Oil, Petroleum 4) Solvent

Final Mix Concentration (lb ai/gal Diluent)_______Total # Gallons Mixed________

# Tank Mixes Monitored_________________ Total Amount of ai Mixed (lb)________

*Tank/Hoppers Capacity (gal/lbs)______________________________________

Other Tank Additives:

- 0) None
- 1) Spreader/Sticker
- 2) Surfactant
- 3) Dye
- 4) Other Pesticide

Study Code No:_______

(EPA Use Only)

MIXER/LOADER/APPLICATOR EXPOSURE SURVEY FORM - 2

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

Describe Mixing Procedures and Equipment____________________

Location of * Data:

Worker I.D.	Work Cycle Number
_____	_____

See Instructions

APPLICATION INFORMATION

*Method of Application:

1) Airblast
2) Groundboom Tractor
3) Groundboom Truck
4) Groundboom Rail Car
5) Aerial - Fixed Wing
6) Aerial - Rotary Wing
7) Low Pressure Hand Wand
8) High Pressure Hand Wand (attached to truck)
9) Backpack
10) Shank Injection
11) Fumigation
12) Solid Broadcast Spreader
13) Liquid Broadcast Spreader
14) Other (describe)

If 14, describe____________________

Rate: (lb ai/acre)_______and (gal/acre)_______ Total lb ai Applied_______

Total # Acres Treated_______ Final Mix Concentration (lb ai/gal Diluent)_______

Total # Gallons Sprayed_______ # Tank Applications Monitored_______

*Vehicle Make and Model:____________________

*Cab Type:

1) Open Cab(Cockpit)
2) Closed Cab(Cockpit)/Window Open
3) Closed Cab(Cockpit)/Window Closed
4) Closed Cab(Cockpit)/Window Closed/Filtered Air

Ground Speed (mph)_____ *Applicator Make and Model:____________________

*Disc # __________ *# Nozzles__________

*Nozzle: Type/Manufacturer__________ Model/No.__________

*Nozzle Pressure (psi)__________ *Boom Height Above Ground (feet)______

*Swath Width (feet)__________ *Length of Boom (feet)__________

*Shank/Probe Type: 1) Knives 2) Sweeps 3) Other

*Depth of Injection/Incorporation (inches)__________

Describe Application Procedure____________________

Study Code No:________

(EPA Use Only)

MIXER/LOADER/APPLICATOR EXPOSURE SURVEY FORM - 3

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

Location of * Data:

Worker I.D.	Work Cycle Number
______	______

See Instructions

WEATHER DATA

% Relative Humidity: High______________ and Low______________

Temperature (Fahrenheit): High___________ and Low______________

Wind Speed: 1) 0-5 mph 2) 6-10 mph 3) >10 mph

Wind Direction Relative to Mixing: 1)Face to Wind 2)Back to Wind 3)Crosswind 4)Other

If 4, explain____

Wind Direction Relative to Travel: 1) Parallel 2) Perpendicular 3) Other

If 3, explain____

PERSONAL CLOTHING

Pants: 0) None 1) Long-legged 2) Short-legged

Shirt: 0) None 1) Long-sleeved 2) Short-sleeved

Jacket: 0) No 1) Yes Shoes/Boots: 0) None 1) Rubber 2) Fabric 3) Leather

PERSONAL PROTECTIVE EQUIPMENT

Protective Suit/Coveralls: 0) None 1) Rubber 2) Fabric 3) Disposable

Hat: 0) No 1) Yes

Eye/Face Protection: 0) None 1) Goggles 2) Face Shield 3) Safety Glasses

Gloves:
0) None
1) Wrist Length Rubber/Plastic
2) Wrist Length Fabric
3) Wrist Length Leather
4) Mid-Forearm Rubber/Plastic
5) Elbow Length Rubber/Plastic

AIRBORNE EXPOSURE DATA

*Technique Used: 1) Filter on Respirator 2) Personal Air Pump 3) Fixed Location

If 3, specify location____

Air Sampling Time (min)________________ Quantification Limit (ug)__________

Amount of Chemical Collected (ug)__________ Air Volume Collected (L)__________

Flow Rate (L/min): Initial____________Final____________Average____________

Study Code No:________

(EPA Use Only)

MIXER/LOADER/APPLICATOR EXPOSURE SURVEY FORM - 4

Worker I.D.	Work Cycle Number
_____	_____

Do Not Leave Blank

DERMAL EXPOSURE DATA Dermal Sampling Time (hrs)__________

Location of * Data:	
Worker I.D.	Work Cycle Number
_____	_____

See Instructions

*Method of Measuring Dermal Exposure Excluding Hands:

1) Patch Technique 2) Solvent Rinse 3) Clothing 4) Other

If 1, describe patch construction (ie. gauze, alpha-cellulose, etc.)____________________

____

If 2, type of solvent____________________

____

If 3, describe clothing____________________

____

If 4, describe____________________

____

*Method of Measuring Hand Exposure: 1) Hand Rinse 2) Gloves 3) Other

If 1, type of solvent____________________

____

If 2, describe gloves____________________

____

____

If 3, describe____________________

____

____

Study Code No:________

(EPA Use Only)

MIXER/LOADER/APPLICATOR EXPOSURE SURVEY FORM - 5

Worker I.D.	Work Cycle Number
______	______

Do Not Leave Blank

Dermal Exposure Values Excluding Hands (ug/cm2):

Location of * Data: Worker I.D.	Work Cycle Number
______	______

See Instructions

Inside Clothing			location (enter 1,2 or 3)	Outside Clothing	
Head	________			________	
Neck Front	________			________	
Neck Back	________			________	
Upper Arms	(R)________	(L)________		(R)________	(L)________
Shoulders	(R)________	(L)________		(R)________	(L)________
Chest	(R)________	(L)________		(R)________	(L)________
Back	(R)________	(L)________		(R)________	(L)________
Forearms	(R)________	(L)________		(R)________	(L)________
Hips	(R)________	(L)________		(R)________	(L)________
Thighs	(R)________	(L)________		(R)________	(L)________
Shins	(R)________	(L)________		(R)________	(L)________
Calves	(R)________	(L)________		(R)________	(L)________
Ankles	(R)________	(L)________		(R)________	(L)________
Feet	(R)________	(L)________		(R)________	(L)________

Average Quantification Limit (ug/cm2)____________________

Hand Exposure Values (ug):

(R)____________________ (L)____________________ Both____________________

Average Quantification Limit (ug):____________________

If incidental contact with the pesticide was observed, please circle the response(s) that best describe(s) the situation:

1) Observed Hand Contact
2) Observed Face Contact
3) Observed Contact with Other Body Parts

Please Provide a Brief Description of the Incidental Exposure Situation________

____

____

____

Study Code No:________

(EPA Use Only)

*QUALITY ASSURANCE SURVEY FORM - 1

This Information Applies to the Following:

Worker I.D.	Work Cycle Number
______	______
______	______
______	______
______	______
______	______
______	______
______	______
______	______
______	______

*See Instructions

Airborne Sampling

Type of Collection Medium______________________________________

Were laboratory recovery efficiencies determined? yes____ no____

Average laboratory recovery efficiency, in percent ____

Coefficient of Variation ____

Were field recovery efficiencies determined? yes____ no____

Average field recovery efficiencies, in percent ____

Coefficient of Variation ____

Was storage stability determined? yes____ no____

Maximum time of storage__________ Average percent recovered__________

Maximum length of time after collection that samples were analyzed____________

Were experimental results corrected for:

a) laboratory recovery? yes____ no____

b) field recovery? yes____ no____

c) storage recovery? yes____ no____

Were field control (blank) samples analyzed? yes____ no____

If contaminated, report level of contamination (ug)____________

Dermal Sampling (excluding hands)

Were laboratory recovery efficiencies determined? yes____ no____

Average laboratory recovery efficiency, in percent ____

Coefficient of Variation ____

Were field recovery efficiencies determined? yes____ no____

Average field recovery efficiencies, in percent ____

Coefficient of Variation ____

Was storage stability determined? yes____ no____

Maximum time of storage__________ Average percent recovered__________

Maximum length of time after collection that samples were analyzed____________

Study Code No:________

(EPA Use Only)

*QUALITY ASSURANCE SURVEY FORM - 2

This Information Applies to the Following:

Worker I.D.	Work Cycle Number
______	______
______	______
______	______
______	______
______	______
______	______
______	______
______	______
______	______

*See Instructions

Dermal Sampling (excluding hands) Continued

Were experimental results corrected for:

a) laboratory recovery? yes____ no____

b) field recovery? yes____ no____

c) storage recovery? yes____ no____

Were field control (blank) samples analyzed? yes____ no____

If contaminated, report level of contamination (ug)____________

Hand Sampling

Were laboratory recovery efficiencies determined? yes____ no____

Average laboratory recovery efficiency, in percent ____

Coefficient of Variation ____

Were field recovery efficiencies determined? yes____ no____

Average field recovery efficiencies, in percent ____

Coefficient of Variation ____

Was storage stability determined? yes____ no____

Maximum time of storage_________ Average percent recovered_________

Maximum length of time after collection that samples were analyzed____________

Were experimental results corrected for:

a) laboratory recovery? yes____ no____

b) field recovery? yes____ no____

c) storage recovery? yes____ no____

Were field control (blank) samples analyzed? yes____ no____

If contaminated, report level of contamination (ug)____________

BELOW DOTTED LINE IS FOR EPA/CONTRACTOR USE ONLY

Quality Control Grade______________________

Appendix B

Exposure Sample History Sheet

EXPOSURE SAMPLE HISTORY

Sample Series ______________

Sample No.	Date Collected	By	Date Extracted	By	Date Analyzed	By

Preextraction Storage: ____

Extraction Procedures: ____

____

____

Analysis: ____

____

____

____

____

Appendix C

Federal Register Notice/Vol. 49 No. 188-
Format of Data Submitted to the Agency

Against Registration or RPAR process) are currently contained in § 162.11(a) and (b). The Agency is considering changes to the criteria and procedures for the special review process at this time, and intends to issue a proposal to revise these regulations.

XVI. Child Resistant Packaging Requirements

New Part 157 would contain the child-resistant packaging requirements currently found in § 162.16. The Agency has recently issued, published in the Federal Register of January 4, 1984 (49 FR 380) final rules revising the criteria and procedures for child-resistant packaging and has proposed a size-based exemption for child-resistant packaging requirements, published in the Federal Register of January 4, 1984 (49 FR 423). Those provisions would be renumbered and designated as Subpart B of Part 157.

That rule required various types of recordkeeping to demonstrate that a package would meet the effectiveness standards, but failed to include a similar requirement with respect to records demonstrating that the compatibility and durability standards are met. This proposal would correct that oversight in § 157.39(d). EPA is proposing no other changes in child-resistant packaging requirements.

XVII. Format of Data Submitted to the Agency

The Agency is proposing to revise 40 CFR Part 158, which defines the data requirements applicable to pesticide registration, by adding new sections establishing format requirements for the data submitted to the Agency. The Agency currently receives a considerable quantity of data in conjunction with its review of registration actions, and will be receiving even more as the Agency's Data Call-In, and reregistration activities accelerate. The Agency can most efficiently review these massive amounts of data if they are submitted in a format that facilitates retrieval and review.

Section 158.32 would require that studies be distinctly identified. Each individual study would have a title page containing identifying information about the study, the pesticide, and the person or organization that conducted the study. Each study would have to be accompanied by a certification in accordance with the Good Laboratory Practice standards of 40 CFR Part 160. All studies submitted at the same time for the same Agency action would be required to be accompanied by a transmittal document identifying all submitters of the material, the Agency action for which the data are submitted, and a bibliography of all studies contained in the transmittal.

In addition, the Agency is proposing format requirements to facilitate EPA compliance with the requirements of FIFRA sec. 10. That section requires that EPA not release certain types of confidential business information. To enable the Agency to recognize such submissions quickly and easily, applicants would be directed to submit material which is clearly and appropriately identified as protected from disclosure.

FIFRA section 10(d) defines as data that may not be disclosed by the Agency the identify and test methods for inert ingredients in pesticides, and manufacturing and quality control processes. Other data submitted to the Agency may generally be disclosed if the Agency determines under FIFRA section 10(b) that it is not trade secret, and provides 30-day notification to the submitter of EPA's intent to release it.

If the Agency is efficiently to administer its responsibilities under the Freedom of Information Act and make pesticide health and safety data available to the public, it must ensure that data not disclosable under section 10(d) are separated from other data that may be released. Under interim procedures published in the Federal Register of December 19, 1978 (43 FR 59060), the applicant is responsible for marking and separating claimed confidential information at the time of submission.

This procedure has not worked satisfactorily in practice, however, because most data submitters assert a claim of confidentiality for all data submitted, without regard to whether it is defined in section 10(d) as disclosable or not. The data submitter is not required to segregate further the data according to its status under section 10. The result is that a data submission generally consists of a mixture of data that may and may not be released. The Agency's policy is to deny claims of confidentiality which pertain to data which are disclosable under section 10(d)(1). When a request for release is received, the Agency has borne the burden of reviewing the data and separating or obliterating that information which is non-disclosable under section 10(d)(1) (A), (B), and (C) from that which the Agency has determined may be released. This is costly and time-consuming and the source of considerable delay in responding to requests under the Freedom of Information Act.

The Agency believes that Congress did not intend that all-inclusive claims of confidentiality should be allowed to impede the release of information which it specifically defined as releasable. Consequently, the Agency is proposing to revise its proposed Part 158 rules to require that a data submitter be required to mark any information which he claims is non-disclosable under section 10(d)(1) (A), (B) or (C) and to separate it from the remainder of the submission. He also may assert a claim of confidentiality for any of the data under section 10(b). If the Agency rejects the 10(b) claim (as is routinely done in the majority of cases), the information covered by the 10(b) claim could be released to a requester promptly. If the submitter fails to identify and separate the 10(d) information, the Agency would not assume any obligation to do so itself, and would release all the information once any 10(b) claim had been resolved. The data submitter would be assumed to have waived his claim of confidentiality for such information.

Section 158.33 would require that information claimed as trade secret under section 10(d)(1) (A), (B), or (C) of the Act be submitted separately and identified by numerical reference within the study. FIFRA section 10(d) defines the types of information that may not be released by the Agency, including manufacturing process, quality control, and identity of and test methods for inert ingredients in a pesticide product. Information not separately submitted and identified as trade secret would be releasable to the public in accordance with Freedom of Information procedures. Information claimed as trade secret under other sections of FIFRA sec. 10 (such as 10(b)) would not have to be submitted separately, but would have to be clearly marked within the body of the study. Separate data confidentiality claims statements (required for each study) would have to be submitted for information claimed to be confidential under section 10(d)(1) (A), (B), and (C) and that claimed confidential under other sections.

In order to distinguish studies that are not marked because they do not contain confidential information from those not marked because they were submitted to the Agency prior to these requirements being established, the Agency is proposing to establish an effective date for §§ 158.32 and 158.33. These sections would become effective for all data received by the Agency approximately 60 days after the effective date of the final rule. A Federal Register document will specify the exact effective date.

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EPA is also considering requiring registrants to screen previously submitted data and either make or waive confidentiality claims for that data. Identification of the trade secret information in all of EPA's data would greatly facilitate processing of requests under the Freedom of Information Act. Studies could be returned to submitters (in microfiche form) in conjunction with the issuance of a Registration Standard or special review. Data submitters would be required to identify those portions of each study that they claim meet the criteria of FIFRA section 10(d)(1)(i) (A), (B), and (C). EPA would like to receive comment on whether such a plan would be feasible (particularly on a phased basis) the costs likely to be incurred, and the problems that might be foreseen if such a program were instituted.

XVIII. Relationship of Proposal to Current Regulations

The following tables compare the current regulations found in 40 CFR Part 162 with those being proposed today. The first table shows where material originally in Part 162 would be located under this proposal, or indicates why it is no longer needed. References to proposed Part 156 appear in a companion document elsewhere in today's Federal Register.

DISTRIBUTION TABLE

Old section	New section
162.1	152.1.
162.2	Deleted: redundant.
162.3	152.3, except as noted.
(a)	Deleted: unnecessary.
(e)	Deleted: unnecessary.
(g)	Deleted: unnecessary.
(h)	See definition of "new use"—152.3(q).
(l)	See definition of "residue"—152.161(c).
(m)	See definition of "residential use"—152.3(w).
(n)	Deleted: unnecessary
(o)	Deleted: unnecessary.
(q)	Moved to Labeling definitions—152.2(b).
(r)	Deleted: unnecessary.
(s)	Moved to Labeling definitions—152.2(c).
(v)	Deleted: unnecessary.
(w)	See definition of "residue"—152.161(c).
(x)	Deleted: unnecessary.
(y)	Deleted: unnecessary.
(z)	Deleted: unnecessary.
(aa)	Deleted: unnecessary.
(bb)	Deleted: unnecessary.
(cc)	See definition of "outdoor use"—152.161(b).
(ee)	152.5.
(gg)	Deleted: unnecessary.
(ii)	Deleted: unnecessary
(jj)	Deleted: unnecessary.
(kk)	See definition of "residue"—152.161(c).
(ll)	See definition of "dietary LC-50"—152.161(a).
(mm)	Deleted: unnecessary.
(nn)	152.3(c), (d), and (e), and 152.161(a).
(oo)	Moved to Labeling definitions—152.2(i).
(pp)	Deleted: unnecessary.
(qq)	Deleted: unnecessary.
(rr)	Deleted: unnecessary.
162.4(a)	152.15.
(b)	152.15
(c)(1)–(5), (6)	152.8 and 152.10 deleted.
162.5(a)	152.15.
(b)(1)–(5)	152.30.
(b)(6)	152.20(b).
(c)	152.20(a).
162.6(a)(1)	152.40.
(a)(2)–(4)	152.50(b).
(a)(5)	152.104 and 152.105.
(b)(1)	152.45, 152.50.
(b)(2)	152.50, except (b)(2)(i)(C)(2)—moved to 158.27.
(b)(3)	152.42(b), 152.50.
(b)(4)	152.42(b)(1)(i).
(b)(5)	Subpart D, §§ 152.60 through 152.79.
(b)(6)	152.102, except (b)(6)(ii)—deleted: unnecessary.
(c)	Deleted: obsolete and unnecessary.
162.7(a)	152.100.
(b)	Deleted: unnecessary.
(c)	152.110.
(d)(1)	152.107.
(d)(2)	152.112.
(d)(3)	152.112.
(d)(4)	Deleted.
(e)	152.111.
(f)	152.118.
(g)	152.119 (published in the FEDERAL REGISTER of August 1, 1984 (49 FR 30884).
162.8(a)	152.50(g)(2).
(b)	152.50(j).
(c)	152.107(c).
162.10	Proposed 40 CFR Part 158.
162.11(a)	Deleted; new regulations will be promulgated.
(b)	Deleted; new regulations will be promulgated.
(c)	Subpart I, §§ 152.160 through 152.179.
162.12	Deleted; not relevant to registration procedures.
162.13	Subpart K, §§ 152.200 through 152.219.
162.14	152.5.
162.15	Subpart M, § 152.240.
162.16	Proposed Part 157, Subpart B.
162.17	Subpart L, §§ 152.220 through 152.239.
162.21(a)	152.45.
(b)	Proposed part 158, Subpart P.
162.22	Deleted: obsolete.
162.23	Deleted obsolete.
162.30	Subpart I, §§ 152.160 through 152.179.
162.31	Subpart I, § 152.171.
162.41 through 162.47.	Deleted redundant and obsolete.
162.50	158.27.
162.160 through 162.177 (Subpart E).	Subsumed in Subparts C, E, F, and H pertaining to submission, review, and disposition of applications.

The following table shows how material in this proposal is derived from Part 162:

DERIVATION TABLE

New section	Old section
152.1	162.1.
152.3	162.3, except as noted.
(i)	162.5(c)(2).
(j)	New.
(k)	162.15.
(l)	162.9–7(c).
(o)	New.
(p)	New.
(s)	162.16(b)(i).
(v)	New.
(w)	New.
152.5	162.14.
152.8(a)	162.3(m)(2)(x).
(b)	162.3(m)(iii)(a) and (13)(x).
(c)(1)	162.4(c)(5).
(c)(2)–(4)	New.
152.10(a)	162.4(c)(1).
(b)	162.3(m)(3)(ii).
(c)	162.4(c)(2), (3), and (4)
(d)	New.
(e)	New
152.15(a)	162.4(b).
(b)	New
(c)	New.
152.20(a)	162.(c)
(b)	162.5(b)(6).
152.25(a)	162.5(d).
(b)	New.
(c)	New.
(d)	162.3(ff)(3)(i)(B).
152.30(a)—(f)	162.5.
(g)	New.
152.40	162.6(a).
152.42(a)	162.6(b)(2).
(b)(1)	New.
(b)(2)	New.
152.45, except (d)	162.6(b)(1), 162.21(a).
(d)	New.
152.50	162.6(b)(2).
(b)	162.6(a).
(c)	New.
(d)	New
(e)	162.6(b)(2)(i)(C).
(f)	162.6(b)(2) and (3), 162.165(b)(2).
(g)(1)	162.6(b)(1).
(g)(2)	162.8(a)(1), 162.163.
(h)	162.16(e).
(i)	162.6(b)(2)(i)(D), 162.165(b)(5).
(j)	162.8(b).
(k)	New
152.55	New.
Subpart D §§ 152.60—152.79.	New.
152.100	New.
152.102	162.6(b)(6).
152.104	162.6(a)(5).
152.105	162.6(a)(5).
152.107	162.7(d).
152.108	New.
152.110	162.7(c).
152.111	162.7(d)(1), 162.7(e).
152.112	162.7(d)(2) and (3).
152.113	162.167(a) and (b).
152.114	New.
152.115	162.167(c).
152.117	New.
152.118	162.7(f), 162.167(e).
Subpart G	New.
Subpart H, except § 152.148.	New.
152.148	162.11(a) and (b), 162.177.
Subpart I, except §§ 152.170, 152.171 and 152.175.	162.30.
152.170	162.11(c).
152.171	162.31.
152.175	New.
Subpart J	New.
Subpart K, except §§ 152.215 and 152.216.	162.13
152.215	New.
152.216	New.
Subpart L	162.17.
Subpart M	162.15.
Subparts N through Q (Reserved).	162.15.
Subpart R	New.
Part 157	162.16.
158.27	162.50.
158.32	New.
158.33	New.
158.1001	162.60

XIX. Statutory Review

In accordance with FIFRA section 25, this proposal was submitted to the Secretary of Agriculture (USDA), the Scientific Advisory Panel (SAP), and the House Committee on Agriculture and Senate Committee on Agriculture, Nutrition and Forestry for comment. No comment was received from either Congressional Committee.

(c) The Agency has concluded that the ingredients listed in § 158.1001 normally have no independent pesticidal activity when included in antimicrobial products. and thus normally are properly classified as inert ingredients of such products. The Agency may determine. on an individual product basis. or the applicant may demonstrate to the Agency's satisfaction. however, that any ingredient listed in § 158.1001 is pesticidally active. In such case. the ingredient shall be listed as an active ingredient on the product label and on the Confidential Statement of Formula.

§ 158.32 Requirements for data submission.

(a) *Transmittal document.* All data submitted at the same time and for review in support of a single administrative action (e.g., an application for registration. reregistration. experimental use permit. or in response to a requirement for data under the authority of FIFRA section. 3(c)(2)(B)) must be accompanied by a single transmittal document including the follwing information:

(1) The identify of the submitter. of all joint submitters. or of the agency for joint submitters. as applicable:

(2) The date of the submission:

(3) The identifying number (if known) of the Agency action in support of which the data are being submitted. such as the registration number or file symbol. petition number. experimental use permit number. or registration standard review; and

(4) A bibliography of all specific documents included in the submission and covered by the transmittal.

(b) *Individual studies.* (1) All data must be submitted in the form of individual studies. Each study should normally address a single data requirement. and be listed separately in the bibliography.

(2) Each study must include the following elements in addition to the study itself:

(i) A title page. as described in paragraph (c) of this section:

(ii) A Statement of Data Confidentiality Claims and. if desired. a Supplemental Statement of Data Confidentiality Claims. in accordance with § 158.33: and

(iii) A certification with respect to Good Laboratory Practice standards. in accordance with 40 CFR 160.12.

(iv) If the original study is not in the English language. a complete and accurate English translation under the same cover.

(3) Two identical copies of each study must be submitted. The copies must be on uniform pages of white paper 8½ x 11 inch size. and have a print quality suitable for microfilming.

(c) *Contents of title page.* Each individual study must have a title page bearing the following identifying information:

(1) The title of the study. including identification of the substance(s) tested and the test name or data requirement addressed:

(2) The author(s) of the study:

(3) The date the study was completed:

(4) If the study was performed in a laboratory. the name and address of the laboratory and any laboratory project numbers or other identifying codes:

(5) If the study is a commentary on or supplement to another previously submitted study. full identification of the other study which it should be associated in review: and

(6) If the study is a reprint of a published document. all relevant facts of publication. such as the journal title. volume. issue. inclusive page numbers. and date of publication.

(d) *EPA document identification number.* Each study will be assigned an EPA Master Record Identification (MRID) number. of which the submitter will be promptly notified. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data.* Data which have previously been submitted need not be resubmitted unless specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action. he should cite the data by providing:

(1) The title or adequate description of the study:

(2) The transmittal information required by paragraph (a) (1). (1). and (3) of this section: and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

§ 158.33 Procedures for claims of confidentiality of data.

(a) *General.* A data submitter must clearly identify any information for which he wishes to assert a claim of confidentiality under FIFRA sec. 10. The procedures in this section must be followed to assert a claim of confidentiality.

(b) *Claims of confidentiality for information described by FIFRA sec. 10(d)(1) (A). (B). and (C).* Any information claimed to be confidential under FIFRA section 10(d)(1) (A) through (C) must be submitted in accordance with the following procedures:

(1) The information must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment. the submitter waives a claim of confidentiality for such information under FIFRA section 10(d)(1) (A). (B). or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA section. 10(d)(1)(A). (B). or (C).

(3) Each item in the attachment must be numbered. For each item. the submitter must cite the applicable portion of FIFRA section 10(d)(1) (A). (B). or (C) on which the claim of confidentiality is based. In addition. for each item. the submitter must provide a list of page numbers in the study where the item is cited (i.e., identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims: "Information claimed confidential on the basis of its falling within the scope of FIFRA section 10(d)(1) (A). (B). or (C) has been removed to a confidential appendix. and is cited by cross-reference number in the body of the study." The statement must bear the name. title. and signature of the submitter or his properly designated agent. and the date of signature.

(c) *No claim of confidentiality under FIFRA 10(d)(1) (A). (B). or (C).* If no claim of confidentiality is being made for information described by FIFRA section 10(d)(1) (A). (B). or (C). or if such information is not contained in the body of the study. the Statement of Data Confidentiality Claims must include the following statement: "No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1) (A). (B). or (C)." This statement must bear the name. title and signature of the submitter or his properly designated agent. and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA section 10(d)(1) (A). (B). or (C).* Any information not described by FIFRA section 10(d)(1) (A). (B). or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures.

(1) The information must be clearly marked in the body of the study as being claimed confidential:

(2) A separate Supplemental Statement of Data Confidentiality

Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

§ 158.1001 Ingredients considered inert when used in antimicrobial products.

The following substances are designated inert ingredients within the meaning of FIFRA section 2(m) when used in antimicrobial pesticide products:

Substance	Uses
Acetone	Solvent.
Alkyl * amino betaine (46 percent C_{12}, 24 percent 3_{14}, 10 percent C^{16}, 6 percent C^{18}, 7 percent C_{10}, 5 percent C_{8}.	Corrosion inhibitor/Surfactant.
Alkyl monoethanolamide	Emulsifier.
Aluminum chloride	Detergent.
Aluminum hydroxybenzenesulfonate sulfonate.	Emulsifier.
Aluminum powder	Filler.
Ammonium carbonate	Detergent.
Ammonium citrate	Sequesterant.
Ammonium lauryl sulfonate	Emulsifier.
Ammonium oleate	Detergent/Emulsifier.
Ammonium oxalate	Detergent.
Amyl acetate	Diluent.
Borax	Detergent.
Butyl alcohol, tertiary,	Solvent/Odorant
Carbon	Carrier/Adsorbent
Castor oil	Emulsifier
Citric acid	Sequesterant.
Diethanolamine dodecylbenzene sulfonate.	Detergent.
Dimethyl phthalate	Perfume.
Disodium monoethanolamine phosphate.	Emulsifier.
Dodecyl benzene sulfonic acid	Detergent.
Essential oils	Perfume
Ethanol (ethyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Ethanolamine	Emulsifier.
Ethanolamine dodecylbenzene sulfonate.	Detergent.
Ethoxylated lanolin	Ointment base.
Ethylenediamine	Emulsifier.
Ethylenediaminetetraacetic acid (including all salts and derivatives.	Sequesterant.
Fumaric acid	Sequesterant.
Gluconic acid	Buffer.
Isooctyl phenoxy polyethoxy ethanol.	Surfactant.
Isopropanol (isopropyl alcohol	Solvent, except in tinctures or where sole or major active ingredient.
Isopropyl myristate	Solvent.
Juniper tar	Odorant.
Lauryl alcohol	Detergent/Odorant.
Lauryl methacrylate	Emulsifier.
Limonene	Odorant/Perfume.
Magnesium chloride	Builder.
Magnesium lauryl sulfate	Detergent.
Magnesium silicate	Odor absorbent.
Menthol	Perfume.
Methanol (methyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Methyl ethyl ketone	Solvent.
Methyl salicylate	Perfume/Odorant
Mineral oil, mineral seal oil or white mineral oil	Lubricant.
Monoethanolamides of the fatty acids of coconut oil.	Emulsifier
Monosodium phosphate	Emulsifier/Buffer
Morpholine	Corrosion inhibitor
Nonylphenoxypolyethoxyethanol.	Surfactant.
Octylphenol	Nonionic surfactant.
Oil of citronella	Perfume/Odorant.
Oil of eucalyptus	Perfume
Oil of lemongrass	Perfume.
Oleic acid	Solvent.
Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, aromatic hydrocarbons, paraffinic oil.	Lubricant/Solvent.
Polyoxyethylene sorbitol, mixed ether ester of.	Emulsifier.
Polyvinylpyrrolidone	Emulsifier.
Potassium bisulfate	Builder.
Polyvinylpyrrolidone	Emulsifier
Potassium bisulfate	Builder.
Potassium carbonate	Detergent.
Potassium dodecylbenzenesulfonate.	Anionic detergent.
Potassium laurate	Emulsifier.
Potassium myristate	Emulsifier.
Potassium N-(3-(nitroethyl) benzyl) ethylenediamine.	Emulsifier.
Potassium phosphate, tribasic	Sequesterant.
Potassium ricinoleate	Emulsifier
Potassium toluene sulfonate	Detergent.
Potassium xylene sulfonate	Detergent.
Propanol (propyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Soap	Detergent.
Sodium acetate	Buffer.
Sodium alkyl (100 percent C^9: benzenesulfonate.	Detergent.
Sodium bicarbonate	Detergent.
Sodium carbonate	Detergent.
Sodium chloride	Builder.
Sodium decylbenzene sulfonate.	Detergent.
Sodium diacetate	Sequesterant.
Sodium dihydroxyethylglycine	Chelate/Buffer.
Sodium diisopropylnaphthalene sulfonate.	Detergent.
Sodium di (monoethanolamine) phosphate.	Emulsifier.
Sodium dodecylbenzene sulfonate (May be active as a sanitizer in dishwashing formulations).	Detergent.
Sodium dodecyl diphenyl oxide sulfonate.	Perfume.
Sodium glycolate	Sequesterant.
Sodium laurate	Detergent.
Sodium N-lauroylsarcosinate	Detergent.
Sodium lauryl sulfate	Detergent.
Sodium metasilicate	Detergent.
Sodium N-methyl-N oleoyl laurate.	Emulsifier.
Sodium mono and dimethyl naphthalene sulfonate.	Detergent.
Sodium oleate	Emulsifier
Sodium phosphate	Emulsifier/Buffers
Sodium salt of Turkey Red Oil	Emulsifier.
Sodium sesquicarbonate	Detergent.
Sodium silicate	Detergent.
Sodium sulfate	Detergent.
Sodium sulfonated oleic acid	Emulsifier.
Sodium thiosulfate	Builder.
Sodium toluene sulfonate	Detergent.
Sodium tripolyphosphate	Sequesterant.
Sodium xylene sulfonate	Detergent.
Tetrapotassium pyrophosphate.	Sequesterant.
Tetrasodium pyrophosphate	Emulsifier.
1,1,1,-Trichloroethane	Diluent.
Triethanolamine	Emulsifier.
Triethanolamine dodecylbenzene sulfonate.	Detergent.
Triethanolamine laurate	Emulsifier.
Triethanolamine lauryl sulfate	Emulsifier.
Triethanolamine myristate	Emulsifier.
Triisopropanolamine	Emulsifier.
Triethanolamine	Emulsifier.
Trisodium phosphate	Detergent.
Turkey red oil	Emulsifier.
Undecylenic acid	Perfume.
Xylene	Solvent.
Zirconium oxide	Dye.

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Subpart A and E—[Removed]

4. By removing Subparts A and E of Part 162.

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